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PTO/SB/21
OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/081,705
Filing Date	February 21, 2002
First Named Inventor	John Barthelow Classen
Group Art Unit	2161
Examiner Name	Etienne Pierre Leroux
Attorney Docket Number	61185.00005

ENCLOSURES (*check all that apply*)

- ☒ Fee Transmittal Form
  - ☒ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s) – Figs.
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s)
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☒ Appeal Communication to TC *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:
  - Brief of Appeal (34 pgs.);
  - Tabs 1 – 7; and
  - postcard

Remarks:

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	**Montgomery, McCracken, Walker & Rhoads, LLP**
Signature	Evelyn H. McConathy
Printed Name	**Evelyn H. McConathy – 35,279**
Date	March 27, 2008

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this paper, along with any documents referred to as being enclosed therewith, is being deposited with the United States Postal Service in an envelope addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on date shown below:.

Typed or printed name	Tara M. Fromm	
Signature	Tara Fromm	Date: March 27, 2008

EXHIBIT A

PTO/SB/17 (02-07)
Approved for use through 2/28/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2007

Fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT | **$770.00**

Complete if known	
Application Number	10/081,705
Filing Date	February 21, 2002
First Named Inventor	John Barthelow Classen
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Art Unit	2161
Attorney Docket No.	61185.00005

METHOD OF PAYMENT *(check all that apply)*

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☐ Deposit Account:
Deposit Account Number **50-2424**
Deposit Account Name **Montgomery, McCracken, Walker & Rhoads, LLP**

For the above-identified deposit account, the Director is hereby authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**
☒ Charge any additional fee required under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

FEE CALCULATION

1. Basic Filing, Search and Examination Fees

Application Type	Filing Fees	Small Entity	Search Fees	Small Entity	Examination Fees	Small Entity	Fees Paid
Utility	300	**150**	500	**250**	200	**100**	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. Excess Claim Fees

Fee Description	Fee	Small Entity
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee	Fee Paid	Multiple Dependent Claims Fee	Multiple Dependent Claims Fee Paid
* - 20 =	×	25 =	**50.00**		

Indep. Claims	Extra Claims	Fee	Fee Paid
* - 3 =	×	100 =	**

3. Application Size Fee

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof.

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee	Fee Paid
*- 100 =	* / 50 =	* (round up to a whole number) ×	*	*

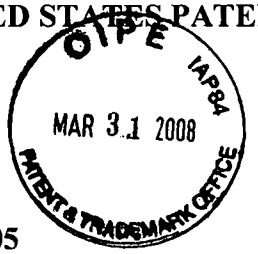
4. Other Fee(s)

	Fees Paid
Non-English Specification, $130 fee (no small entity discount)	
Other: Appeal Brief Fee and Request for Oral Hearing Fee	$770.00

SUBMITTED BY

Name (Print/Type)	Evelyn H. McConathy	Registration No. (Attorney/Agent)	35,279	Telephone	(215) 772-7550
Signature	Evelyn H. McConathy			Date	March 27, 2008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Application of:

John Barthelow Classen **Attorney Docket: 61185.00005**

Application No.: 10/081,705 **Group Art Unit: 1273**

Filed: 02/21/2002 **Examiner: LEROUX, Etienne Pierre**

Title: ***Computer Algorithms and Methods for Product Safety***

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL UNDER 37 C.F.R. § 1.192

Sir:

This Appeal Brief is submitted with all necessary fees in support of the Notice of Appeal filed January 28, 2008, and in Response to the Office Action dated August 31, 2007. An oral hearing is requested. No additional fee is believed to be due in this filing. However, if a fee is due, the Office is authorized to withdraw the necessary amount from Deposit Account 50-2424.

04/01/2008 EFLORES 00000002 10081705
01 FC:2402 255.00 OP

04/01/2008 EFLORES 00000002 10081705
02 FC:2403 515.00 OP

I. Real Party in Interest

Real Party in interest is the Owner by Assignment: Classen Immunotherapies.

II. Related Appeals and Interferences

Inventor, John Barthelow Classen, and Owner by Assignment, Classen Immunotherapies, independently and collectively, along with their undersigned legal representative, are unaware of any appeals or interferences that are related to the instant Appeal, or that will affect, be affected by, or have any bearing on, the Board's decision in the instant Appeal.

III. Status of the Claims

Claims 250 – 300 are currently pending in the application. Claims 250 – 300 stand rejected in the outstanding Office Action dated August 31, 2007 under 35 U.S.C. § 103(a). Claims 250, 256, 257, 270 – 276, 278, 281, 282, 285 – 290, 292 and 294 – 298 are rejected under 35 U.S.C. § 103(a) as being unpatentable over applicant disclosed prior art (ADPA) in view of Pub. No. 2002/0039990 (Stanton), further in view of U.S. Patent No. 5,991,751, issued to Rivette (Rivette), further in view of U.S. Patent No. 6,458,958 issued to D'Ambra (D'Ambra). Claims 251, 252, 254, and 279 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette, and D'Ambra and further in view of U.S. Patent No. 5,678,234 issued to Colombo (Colombo). Claims 253 and 255 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette, D'Ambra and Colombo and further in view of US Patent No. 6,018,714 issued to Risen (Risen). Claims 259, 260 – 269, 277, 283, 284, and 291 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette, and Risen. Claims 299 and 300 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette and further in view of U.S. Patent No. 3,885,566 issued to Jacob (Jacob).

As originally filed on February, 21, 2002, the application was filed claiming priority to U.S. Provisional Application No. 60/270,697 filed on February 22, 2001. The original filing contained 200 claims.

A first non-final Office Action was mailed on December 30, 2005, withdrawing claims 1 – 32 and 85 – 200 from consideration, and rejecting claims 33 – 84 under 35 U.S.C. § 112, first paragraph for enablement and § 102(b) as anticipated by U.S. Patent Pub. No. 2001/0001144 issued to Knapp, as well as under § 103(a) in light of Knapp and further in view of U.S. Patent Pub. No. 2002/0082930 issued to Park. On January 30, 2006, Applicant responded to the Office Action of December 30, 2005 by amending claims 33, 39 – 41; canceling claims 1 – 32, 42 – 45 and 64 – 200201 – 249; and adding claims 201 – 249.

The Examiner issued a Final Office Action on March 20, 2006 responsive to Applicants' arguments of January 30, 2006. The Action included a statement confirming a telephonic election of claims 201 – 246 without traverse. In the Final Office Action of March 20, 2006, claims 201 – 213 and 215 – 246 were rejected. The Examiner noted that claim 214 was missing. In addition, a nonstatutory double patenting rejection was lodged over claim 15 of U.S. Patent

No. 6,219,674 issued to Classen. Claims 210, 203, 205 – 207, 209 – 211, 216, 217, 220, 221, 225 – 228, and 231 – 245 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,726,884 issued to Sturgeon et al in view of U.S. Patent No. 6,944,776 issued to Lockhart et al. Claim 202 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sturgeon and Lockhart, further in view of U.S. Patent No. issued to Diamond. Claims 204 and 244 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sturgeon and Lockhart, further in view of U.S. Patent No. 6,221,851 issued to Feldman. Claim 208 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sturgeon and Lockhart, further in view of Applicants' admitted prior art. Claims 212, 213, 215, 218, 219, 229, and 230 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sturgeon and Lockhart further in view of U.S. Patent No. 5,950,630 issued to Portwood. Claims 222 – 224 and 246 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Sturgeon and Lockhart further in view of U.S. Patent No. 6,097,995 issued to Tipton et al.

A response was filed on May 22, 2006 by Applicant confirming the previous election of claims 201 – 213 and 215 – 249 for patent prosecution and adding new claims 250 and 251. No other amendments to the claims were made.

The Examiner then issued an Advisory Action on June 23, 2006, rejecting claims 201 – 213 and 215 – 246, and stating that proposed amendments (the addition of claims 250 and 251) would not be entered. Applicant filed a Request for Continued Examination on July 11, 2006, along with a response reiterating arguments presented on May 22, 2006. Claims 201 – 213, 215 – 249 and 250 and 251 remained pending.

The Examiner responded by issuing a non-final Office Action on August 18, 2006, rejecting claims 201 – 213 and 215 – 251 under 35 U.S.C. § 112, second paragraph, and under 35 U.S.C. § 101 for the judicial exception of natural phenomenon. In addition, a nonstatutory double patenting rejection was lodged against claim 201 as being unpatentable over claim 15 of US Patent No. 6,219,674 issued to Classen.

On October 20, 2006, Applicant, Applicant's representative and the Examiner participated in an interview regarding the nature of the invention, the rejection under 35 U.S.C. § 101 and further defining method steps. Shortly thereafter, Applicant filed a response to the outstanding Office Action of August 18, 2006 on November 20, 2006, canceling claims 201 –

249 and adding claims 252 – 294, thus claims 250 – 294 remained pending.

On January 4, 2007, the Examiner issued a Final Office Action, rejecting claims 250 – 294. Claim 250 was rejected under 35 U.S.C. § 112, first paragraph and second paragraph, as well as rejected under 35 U.S.C. § 101 for the judicial exception of natural phenomenon. Claims 250, 256 and 257 were rejected under 35 U.S.C. § 103(a) over US Patent No. 6,000,828 issued to Leet (Leet) in view of US Patent No. 5,991,751 issued to Rivette (Rivette). Claims 251, 252, 254 and 258 were rejected under 35 U.S.C. § 103(a) over the combination of Leet/Rivette further in view of US Patent No. 5,678,234 issued to Colombo (Colombo). The Examiner went on to state that all remaining claims could be "rejected over prior art of record".

Applicant then filed a Request for Continued Examination on March 29, 2007, along with a response. Claims 250 – 294 were amended and new claims 295 – 300 were added. A Declaration under 37 C.F.R. § 1.132 by John Barthelow Classen, MD, was submitted together with – and in support of – Applicant's response. A copy of the Declaration as filed is submitted herewith and attached hereto.

A Non-Final Office Action was issued by the Examiner on May 11, 2007. Claims 250, 285 and 298 were rejected under 35 U.S.C. § 112, first paragraph. Claims 280 and 293 were rejected under 35 U.S.C. § 112, second paragraph. Claims 250, 256, 257, 270 – 276, 278, 281, 282, 287 – 290, 292, and 294 – 297 were rejected under 35 U.S.C. § 103(a) as being unpatentable over ADPA in view of Pub. No. 2002/0039990 (Stanton), further in view of U.S. Patent No. 5,991,751, issued to Rivette (Rivette). Claims 251, 252, 254, 258 and 276 were rejected under 35 U.S.C. § 103(a) over ADPA, Stanton, Rivette, further in view of US Patent No. 5,678,234, issued to Colombo (Colombo). Claims 259, 260, 261 – 269, 277, 283, 284, and 291 were rejected under 35 U.S.C. § 103(a) over Stanton, Rivette, further in view of US Patent No. 6,018,714 issued to Risen (Risen). Finally, claims 299 and 300 were rejected over Stanton, Rivette further in view of US Patent No. 3,885,566 issued to Jacob (Jacob).

Applicant filed a response on August 13, 2007 to the Action of May 11, 2007. Claims 250 – 300 remained pending, while claims 250 – 253, 255 – 259, 270 – 273, 278, 280 – 282, 285 – 290, 293, 296, and 298 – 300 were amended. The Examiner, however, issued a Final Office Action on August 31, 2007 in response to Applicants' amendment, the substance of which is summarized above, and is the basis for Applicant's present appeal.

IV. Status of Amendments

No amendments have been made to the claims since Applicant's Response dated August 13, 2007.

V. Summary of the Claimed Subject Matter

Claims are pending in Applicant's application. Claim 250 is the independent claim, and all other pending claims are directly or indirectly dependent upon claim 250. As previously amended, pending claim 250 reads as follows:

> 250. A proprietary method of use for a product of manufacture or device, wherein the use was established according to the steps comprising:
>
> accessing one or more data sources, wherein at least one data source comprises adverse event data;
>
> analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device;
>
> identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, and then responsive to identifying of the essential adverse event, identifying the at least one previously unreported method of use for, the product or device;
>
> documenting inventorship of the at least one method of use for the product or device; and
>
> creating a database of proprietary essential adverse event information, the database storing data regarding the at least one essential adverse event, wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, and
>
> wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof.

As Applicant explains in the background of the invention, systems and methods for screening databases to determine new adverse events and to develop proprietary new uses and proprietary kits containing warnings pertaining to the new adverse event information are less than ideal because not all adverse event information is commercially valuable.

The prior art has failed to contemplate business methods which involve detecting essential adverse events relating to a product or device, and then offering the refined proprietary data from such screens to the manufacturers and/or distributors of the product or device. Once the existence of such essential adverse data is known to the manufacturer and/or distributor, they are obligated to inform the public of the potential adverse event, or they must remove the product

or device from the market. The term "essential" adverse event information refers to specific adverse event information that a manufacture must disclose since not all adverse event information must be disclosed. Often only potentially serious adverse event information must be disclosed. Because manufacturers are currently producing and distributing products and devices without restrictions on their use, they are available for use in screens to develop essential adverse event data, which when refined, would become proprietary. There exists a substantial market for such refined, proprietary, essential adverse event data, and for the methods, systems and devices by which it is obtained, which would (1) meet the need in the art for steps which would enhance public safety with regard to the use of products and devices, and (2) offer to manufacturers and/or distributors of product and/or devices a way to (a) significantly improve public safety, (b) permit their products and devices to remain on the market, and (c) reduce their risk of liability for the occurrence of an adverse event with the use of their products or devices.

Applicant's invention permits not only ways of screening for new, previously unrecognized adverse events associated with the use of a product or device, but also a method for developing new proprietary and commercially valuable uses of a product responsive to identifying the new "essential" adverse events. The method permits a technician or computerized system to detect new essential adverse events and identify new useful characteristics or uses for a product or device, and commercialize the essential adverse data information.

Support for Independent Claim 250

Element of claim	Support for element
A proprietary method of use for a product of manufacture or device, wherein the use was established according to the following steps comprising:	See *e.g.*, Abstract and Summary, and paragraphs 0007, 0013 and 0014 and 0027.
accessing one or more data sources,	See *e.g.*, paragraphs 0028, 0032, 0033.
wherein at least one data source comprises adverse event data;	See *e.g.*, ref character 12 in Fig. 1 and step 26 in Fig. 4.
analyzing and comparing adverse event data associated with a product of manufacture or device,	See *e.g.*, paragraphs 0011, 0032, 0037.
with at least one previously known adverse event associated with the product or device;	See *e.g.*, paragraphs 0011, 0040.
identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event	See *e.g.*, paragraphs 0040, 0042, 0050, 0051, 0056.

data,	
and then responsive to identifying of the essential adverse event, identifying the at least one previously unreported method of use for the product or device;	See *e.g.*, paragraphs 0011, 0056, and step 28 in Fig. 4.
documenting inventorship of the at least one method of use for the product or device; and	See *e.g.*, paragraph 0069.
creating a database of proprietary essential adverse event information, the database storing data regarding the at least one essential adverse event,	See *e.g.*, steps 29 and 30 in Fig. 4.
wherein the database comprises at least one of: a patent, patent applications, patent publication, or data contained in at least one patent, patent application or patent publication, and	See *e.g.*, paragraph 0069.
wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof.	See *e.g.*, paragraphs 0071, 0072, 0074 and step 33 in Fig. 5 and Fig. 6.

VI. Grounds for Rejection to be Reviewed on Appeal

1. Examiner's rejection of claims 250, 256, 257, 270 – 276, 278, 281, 282, 285 – 290, 292 and 294 – 298 under 35 U.S.C. §103(a) as being unpatentable over applicant disclosed prior art (ADPA) in view of Pub. No. 2002/0039990 (Stanton), further in view of U.S. Patent No. 5,991,751, issued to Rivette (Rivette), further in view of U.S. Patent No. 6,458,958 issued to D'Ambra (D'Ambra).

2. Examiner's rejection of claims 251, 252, 254, 258 and 279 under 35 U.S.C. §103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette, and D'Ambra, further in view of U.S. Patent No. 5,678,234 issued to Colombo (Colombo).

3. Examiner's rejection of claims 253 and 255 under 35 U.S.C. §103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette, D'Ambra and Colombo and further in view of US Patent No. 6,018,714 issued to Risen (Risen).

4. Examiner's rejection of claims 259, 260, 261 – 269, 277, 283, 284 and 291 under 35 U.S.C. §103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette, and Risen.

5. Examiner's rejection of claims 299 and 300 under 35 U.S.C. §103(a) as being unpatentable over the combination of ADPA, Stanton, Rivette and further in view of U.S. Patent No. 3,885,566 issued to Jacob (Jacob).

VII. Argument

Applicant respectfully submits that the Examiner has erred in rejecting claims 250 – 300 under 35 U.S.C. § 103(a). In the following, Applicant presents arguments and evidence in support of his position. Some of the evidence is based on the Declaration of John Barthelow Classen (Classen) and attachments thereto, entered into the prosecution record under 37 C.F.R. § 1.132 on March 29, 2007, and duplicated in this Brief in the Evidence Appendix. All citations to this Declaration found in this Brief refer to the Evidence Appendix copy. Other evidence is presented from Applicants' record, which is also attached in this Brief in the Evidence Appendix.

1. Re: Claim Rejection under 35 U.S.C. § 103(a) over the combination of ADPA, Stanton and Rivette and D'Ambra:

The Examiner has rejected Applicant's claims 250, 256, 257, 270-276, 278, 281-282, 285, 286, 287-290, 292, and 294-298 under 35 U.S.C. §103(a), as obvious and unpatentable over applicant disclosed prior art (ADPA) in view of Stanton (US Pub. No. 2002/0039990), further in view of Rivette (US Pat. No. 5, 991,751), and further in view of D'Ambra (US Pat. No. 6,458,958). In making this rejection the Examiner refers to ADPA as found in paragraph [0050]. Applicant has no way of knowing which specific "prior art" the Examiner is referring to, but did find that paragraph [0050] refers to "Sources of prior known essential adverse events can include package inserts, the Physician's Desk Reference, The Merck Manual, data from regulatory agencies such as the FDA, and published literature found on databases such as MEDLINE."

It must be noted that Applicant does NOT admit that such statement or any statement in paragraph [0050] identifies "prior art" to Applicant's claimed invention. Applicant admits only the he has identified "sources of prior known essential adverse events" – but this is not the subject matter claimed in Applicant's invention. Consequently, no admission of the type referred to by the Examiner has been made by Applicant, and no admission has been made as to any prior art as to the subject matter actually claimed by Applicant to define his invention.

Moreover, the Stanton publication specifically underlies all of the Examiner's patentability rejections. However Stanton was published April 4, 2002 (almost 1 year after the effective filing date (February 22,2001) of the Applicant's provisional application number 60/270,697. 35 U.S.C. §103(a) states that "A patent may not be obtained though the invention is

not identically disclosed or described as set forth in section 102 of this title." And 35 U.S.C. §102 states that "A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or - - -

(e) the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent. . . ."

Thus, none of these limitations is meet by the Stanton reference, which offers neither a written description, nor a printed publication BEFORE the earliest effective filing date of Applicant's invention, and it is quite simply not permitted prior art against Applicant's invention. As such all rejections based on Stanton as the underlying reference must therefore fail, as being based on an improper prior art reference. Accordingly, Applicant asks that all 103 rejections be removed and the Applicant's application be found patentable.

Nevertheless, in an effort to respond fully and completely to all possible issues before the Board of Appeals, Applicant will address the cited references combined with the ADPA.

Regarding the Examiner's arguments of Stanton in view of Rivette, Stanton's publication relates expressly to genetic screening (see title "Gene Sequence Variances in Genes Related to Folate Metabolism having Utility in Determining the Treatment of Disease"). The Stanton abstract specifies "Methods of determining relevant variance information and additional methods of using such variance information are also described." The specifications in particular mentions defines the invention as relating expressly to "pharmacogenetic studies" see, *e.g.*, paragraphs 6, 124, 136, 157, 194,195, 196, 197, 297, 300, 301, 302, 303, 305-311, 312, 314-318, 327, etc. Thus, in Stanton's own words, his invention is based on pharmacogenics. See Stanton paragraph [0157]:

> [0157] Practice of this invention will often begin with identification of a specific pharmaceutical product, for example a drug, that would benefit from improved efficacy or reduced toxicity or both, and the recognition that

> pharmacogenetic investigations as described herein provide a basis for achieving such improved characteristics.

By contrast, Applicant's invention *expressly* excludes pharmogenetics/ pharmacogenomics. The terms can be used interchangeably. See Applicant's specification at paragraph [0103]:

> [0103] Nevertheless, the present invention is not intended to encompass pharmacogenomic techniques for screening.

A description of this difference can be found in Applicant's earlier patent (See, US patent 6,584,472 (Classen) at column 5, paragraph 3) which is included by reference and cited in the present application (see Applicant's present application at paragraph [0003] referencing U.S. Ser. No. 09/804,289). See also the disclaimers (Classen application, paragraphs [0114], [0115]), which include the cited Classen patent and teachings by reference.

The cited paragraph in the Classen '472 patent states at col. 5, para 3 that:

> Pharmacogenetics and pharmacogenomics are fields dedicated to determining the genetic basis for pharmaceutical phenomenon, such as drug metabolism. For example pharmacogenetics has been utilized to determine why some individuals metabolized a drug faster than another. This approach has been successful when a single enzyme is responsible for the event. Pharmacogenomics is similar to pharmacogenetics, but involves studying the effects of multiple different genes on a characteristic, such as drug metabolism or adverse event. The goal of these fields is to develop genetic tests to individualize pharmaceutical treatment based on a person's genes. However, these fields do not involve screening databases for new adverse events, rather they start with a defined adverse event, and then attempt to determine the molecular cause of the event. If the pharmacogenetic study leads to a new use, that use involves the use of specific laboratory test, usually a molecular test, in conjunction with the administration of the selected drug. In this situation a prospective clinical trial is needed before regulatory approval, *i.e.*, FDA approval, of the new use. Thus, the new use is not the result of the discovery of the adverse event; it is the product of the clinical trial.

Applicant's exclusion of pharmacogenomics/genetics was not simply to exclude prior art, but because the methods are distinctly different - as clearly seen between the teachings of Classen and Stanton.

Moreover, Stanton fails to make any reference of any kind to an adverse event as being either "new" or "essential." Further, the Stanton claimed method of use is not "responsive" to

identifying a new or previously-unreported, essential adverse event; rather it refers only to a clinical trial program. At paragraph 293-297, Stanton states, *e.g.*, that a clinical trial is needed to test the "therapeutic invention" (Stanton paragraph 296). This is to be expected and remains consistent with the definition of pharmacogenomics with regard to the Stanton invention.

In marked contrast, according to Applicant's invention there is *no clinical trial required*, nor does such a trial provide the necessary warning(s). Furthermore, if a regulatory agency requires a clinical trial before it will approve a sponsor to provide the public with information, as is the case with Stanton's published application, then the resulting data is not "essential" since a regulatory body does not require that the information be made public, but instead is permitting the release of the information **only** if there is sufficient clinical trial data supporting its use. Thus, the Stanton method of using the information is not comparable to Applicant's claimed method of use because Stanton's method is NOT "responsive" to discovering a previously-unreported essential adverse event but the result of a clinical trial program. The Stanton invention comprises a kit containing at least one probe (Stanton paragraph [0075]). This requires use in the clinical trial of a probe "approved by a regulatory agency." By contrast, kits described by Applicant (see paragraph [0079]) which provide warnings – DO NOT require regulatory approval to place the new adverse event information.

Stanton teaches that the inventive "process of 'identifying' or discovering new variances involves comparing the [nucleotide] sequence of at least two alleles of a gene." (Stanton , paragraph [0035]). Again this refers to expressly to pharmacogenetics. Furthermore Stanton states at paragraph [0036] that "The process of determining involves using diagnostic tests for specific variances or variant forms of gene (genes)." This again refers to pharmacogenetics. By contrast, however, although Stanton at paragraph [0019] and [0114] refers to "adverse events," Stanton never states or even suggests that the adverse event is "essential" as defined by Applicant, nor that it is "new" or "novel" or "previously unreported" or unknown – as would be required of an inventor conceiving of a proprietary invention. Consequently, Stanton makes no requirement that the "adverse event" MUST be "new" or "novel" or "previously unreported" or unknown.

What is patentable in Stanton's publication, if anything is patentable, is only the information about the gene variance and the "old" or "known" or "previously reported" adverse event. Stanton lists adverse events at paragraph [0017], including nausea, weakness, dizziness,

diarrhea, but Stanton does not claim these adverse events are themselves "new," nor does Stanton's invention require that they be new. These types of adverse events were likely reported at an early stage for all drugs.

In fact, the difference between Applicant's requirement that the essential adverse events must be "previously unreported" (meaning novel) and Stanton's use of known information becomes abundantly clear in Stanton's paragraph [0053], where Stanton expressly admits that "the variance may be *previously known.*" Furthermore Stanton states in the last paragraph, that "Such demonstration can be beneficial, for example, for obtaining government regulatory approval for a new drug or a new use of a drug." Stanton actually teaches away from Applicant's required "essential" adverse event, since the term "essential" as defined by Applicant, implies a manufacture must disclose the adverse event information - as opposed to getting government approval (or approval from a regulatory agency) before disclosing the information - as taught by Stanton.

Accordingly, because Stanton requires a gene database (paragraph [0099]) as a critical element of the invention, which element is expressly excluded from Applicant's invention (paragraph [0103]), Stanton is not prior art to Applicant's invention. The Stanton database is not an "adverse event database" as described by Classen and does not mention a "novel *essential* adverse event." Thus, Stanton fails to teach each and every claim elements or limitations of Applicant's invention. To fill that deficiency, the Examiner has relied upon Rivette and D'Ambra.

Rivette fails to teach or even mention creating a "database of proprietary essential adverse event data." While Rivette does mention a patent database, the claim limitation mentions a specific type of patent database.

While D'Ambra discloses (column 1 , lines 50-65) "side effects" which is a subset of the more broadly defined "adverse events," D'Ambra never teaches to discover new adverse events how these old "side effects" can be turned into "proprietary new uses." D'Ambra never teaches how to patent "side effects" nor that one should patent "side effects." Furthermore D'Ambra never teaches to find new proprietary uses to avoid these adverse events. It is unclear from D'Ambra how to avoid side effects like sedation, GI distress, dry mouth, constipation, and or diarrhea. D'Ambrosa actually teaches away from Classen by teaching to develop new proprietary

derivatives of Terfadine rather develop new proprietary uses for Terfadine responsive to identifying new adverse events.

D'Ambra at Col 1, lines 52 – 65 teaches:

> Side effects reported with terfenadine are cardiac arrhythmias (ventricular tachyarrhythmias, torsades de points, ventricular fibrillation), sedation, GI distress, dry mouth, constipation and/or diarrhea. The most serious of these, and potentially life threatening, are cardiac arrhythmias, which are related to terfenadine's ability to prolong the cardiac QT interval, and are only reported in patients administered terfenadine with liver disease or who also take the antifungal drug ketoconazole or the antibiotic erythromycin. As a result of these adverse events, the FDA, in 1992, required terfenadine to include a warning label. Although OTC formulations of terfenadine are purportedly being developed, the potentially serious side effects seen in some patients will be a significant obstacle for regulatory approval.

Furthermore side effects like dry mouth and diarrhea may not be essential, since in order to be essential they must be potentially serious enough that a manufacture must warn about the reaction. D'Ambra does not teach to separate "side effects" from "essential" side effects. In fact, D'Ambra also does not teach how to screen for "adverse events," other than side effects, such as low efficacy.

Applicant asserts that it is insufficient to conclude that a claim is obvious just because features of a claim might be independently suggested in the prior art. Rather, there must be some predictable use of prior art elements according to their established functions. Applicant respectfully asserts that the combination of Stanton, Rivette, and D'Ambra does not allow a "predictable use of the prior art elements according to their established functions."

Thus, neither Stanton nor Rivette, nor D'Ambra, alone or in combination, teach or suggest a database of "proprietary essential adverse events." Hence, even if combined, deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art. Consequently, in accordance with patent law, if the cited prior art fails to teach each and every element of Applicant's invention, there can be no finding of obviousness of the cited claim. It is respectfully asserted, therefore, that the rejection of Applicant's claims under 35 U.S.C. §103(a) over ADPA, Stanton, Rivette and D'Ambra is improper and should be reversed.

2. **Re: Claim Rejection under 35 U.S.C. § 103(a) over the combination of ADPA, Stanton, Rivette, D'Ambra and Colombo**:

The Examiner has rejected Applicant's claims 251, 252, 254, 258 and 279 under 35 U.S.C. §103(a), as obvious and unpatentable over applicant disclosed prior art (ADPA) in view of Stanton (US Pub. No. 2002/0039990), Rivette (US Pat. No. 5,991,751), and D'Ambra (US Pat. No. 6,458,958) in further view of Colombo (US Pat. No. 5,678,234). In making this rejection the Examiner relies upon ADPA, Stanton, Rivette and D'Ambra for the reasons previously stated, and adds Colombo to disclose the value of commercialization.

Examiner relies on Colombo at 3 lines 60 -65. Careful review, however, shows that the Colombo passage has nothing to do with the claim limitations in Applicant's claims 251, 252, or 254. These claims relate to determining the "value of commercialization," which is defined in the specification paragraphs 123-127, under the Heading "Methods of Screening Adverse Events For Commercial Value."

> [0124] All adverse event information is not of equal value. "Commercial value" depends on the potential value of making a generic product or device into a proprietary product or device, or preventing a proprietary product or device from becoming a generic product or device. "Potential commercial value" or "commercial value," as used herein, means whether it is in the financial interest of an individual or company to seek intellectual property rights on new adverse event information. It can also mean the quantifying of value or projected value based upon obtaining intellectual property rights to the adverse event information.

For the above-stated reasons, ADPA, Stanton and Rivette fail to disclose, suggest or render Applicant's claim 250 or any claim dependent thereon obvious. As a result, simply adding knowledge of determining the value of commercializing a product, as proposed by Examiner with the Colombo reference, still leaves one of ordinary skill in the art unable to determine an "essential" adverse event or to act with a method of use "responsive" to such a new essential adverse event.

As such none of the cited references, including Colombo, alone or in combination teach or suggest a database of "proprietary essential adverse events." Hence, even if combined, deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art. It is respectfully asserted, therefore, that the rejection of Applicant's claims under 35 U.S.C. §103(a) over ADPA, Stanton, Rivette, D'Ambra and Colombo is improper and should be reversed.

3. **Re: Claim Rejection under 35 U.S.C. § 103(a) over the combination of ADPA, Stanton, Rivette, D'Ambra, Colombo and Risen**:

The Examiner has rejected Applicant's claims 253 and 255 over ADPA, Stanton, Rivette, Colombo, and Risen (US Patent No. 6,018,714). In making this rejection the Examiner relies upon ADPA, Stanton, Rivette, and Colombo for the reasons previously stated, and adds Risen for the teaching of incorporating information into documents for selling, leasing or licensing the identified product information regarding a step of disclosing the value of commercialization.

The Examiner cites Risen patent for its "commercialization step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information."

The Risen abstract reads:

> Disclosed herein is a method of providing protection against an unexpected change in value of an intellectual property asset, which includes: (a). obtaining a description of at least one intellectual property asset of a first party, (b). determining a value of the at least one intellectual property asset, (c). determining a cost of providing compensation for an unexpected change in value of the at least one intellectual property asset, and (d). offering to provide compensation for at least a portion of any unexpected change in value of the at least one intellectual property asset to a person with an interest in the first party. A corresponding data processing system, insurance proposal form and computer-generated insurance policy form also are disclosed. The method, system and forms of the invention can be used, for example, as part of a "due diligence" analysis in the context of the purchase and/or sale of intellectual property assets."

Applicant responds that Risen describes a system for providing insurance if the value of an intellectual property decreases. However, Risen's teachings are irrelevant to Applicant's claims 253 and 255 which relate to "*commercialization*," specifically as the invention relates to obtaining profit from sale of adverse event information. In fact, Risen fails to describe how one would generate additional profit from selling products with additional or novel adverse event information in their marketing sale information. This distinction is particularly true since in the past new adverse event information had always been included in pharmaceutical package inserts without generating additional profit. Commercialization of an adverse event has to do more than simply placing a warning on a label. One has to obtain specific profit for having it on the label and that value must be generated through a sale, as opposed to a use of a product.

The definitions of "commercialize" and "commerce" are provided from Webster's dictionary (http://www.m-w.com). "Commercialize" means a) to manage on a business basis for

profit; b) to develop commerce in. "Commerce" means the exchange or buying and selling of commodities on a large scale involving transportation from place to place. This is not provided by Risen to fill the deficiency in the Examiner's finding that Applicant's invention is obviousness when Stanton, Rivette and Colombo are combined.

For the above-stated reasons, ADPA, Stanton, Rivette and Colombo fail to disclose, suggest or render Applicant's claims 253 and 255, or any other claims, obvious. Simply adding information into documents for selling, leasing or licensing the identified product information still leaves one of ordinary skill in the art unable to determine an "essential" adverse event or to act with a method of use "responsive" to such a new essential adverse event. As such none of the cited references, including Risen, alone or combined, suggest a database of "proprietary essential adverse events." Hence, even if combined, deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art. It is respectfully asserted, therefore, that the rejection of Applicant's claims under 35 U.S.C. §103(a) over ADPA, Stanton, Rivette, D'Ambra, Colombo and Risen is improper and should be reversed.

4. Re: Claim Rejection under 35 U.S.C. § 103(a) over the combination of ADPA, Stanton, Rivette, and Risen:

The Examiner has rejected Applicant's claims 259 – 269, 277, 283, 284 and 291 over ADPA, Stanton, Rivette, and Risen.

For the reasons stated above in regard to the rejection of claims 253 and 255, ADPA, Stanton, and Rivette fail to disclose, suggest or render Applicant's claim 250 or any claim dependent thereon obvious. Again, simply adding information into documents for selling, leasing or licensing the identified product information still leaves one of ordinary skill in the art unable to determine an "essential" adverse event or to act with a method of use "responsive" to such a new essential adverse event. As such, none of the cited references, including Risen, alone or combined, suggest a database of "proprietary essential adverse events." Hence, even if combined, deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art. The Examiner has attempted to fill the void between the references and Applicant's invention by taking Official Notice of six items. (See Office Action of August 31, 2007 at page 7.)

Indeed, the gaps between the cited art and Applicant's invention are great, however, relying on facts such as: raw commercial or sales data, proprietary information, medical

products, non-medical products, product exposure time, and date of inventorship, as the Examiner has done in the rejection under § 103(a), does nothing to fill the void. Specifically, the facts of which the Examiner has taken Official Notice do not provide one skilled in the art to arrive at Applicant's invention because one would not arrive at a database of "proprietary essential adverse events" given the additional facts. Moreover, Applicant respectfully asserts that reliance on facts to support six elements of Applicant's claims, that could not be found in a combination of over four references, further supports Applicant's assertion that the Examiner has erred in making the § 103(a) rejection. Furthermore, the rejection discussed herein and presented by the Examiner in the Office Action at page 7 is unsupported by reasons as to *why* Applicant's invention would be obvious in light of the references cited under 35 U.S.C. § 103(a) and in light of Official Notice taken of facts (facts of which are unsupported by references) as required by MPEP 2144.03. The MPEP at 2144.03 states, in part:

> Official notice without documentary evidence to support an examiner's conclusion is permissible only in some circumstances. While "official notice" may be relied on, these circumstances should be rare when an application is under final rejection or action under 37 CFR 1.113.
>
> It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21.
>
> If such notice is taken, the basis for such reasoning must be set forth explicitly. The examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. See *Soli*, 317 F.2d at 946, 37 USPQ at 801; *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. The applicant should be presented with the explicit basis on which the examiner regards the matter as subject to official notice "so as to adequately traverse the rejection" in the next reply after the Office action in which the common knowledge statement was made.

As such, it is respectfully asserted that the rejection of Applicant's claims under 35 U.S.C. §103(a) over ADPA, Stanton, Rivette and Risen, supplemented with Official Notice taken of facts unsupported by documentary evidence, is improper and should be reversed.

5. **Re: Claim Rejection under 35 U.S.C. § 103(a) over the combination of ADPA, Stanton, Rivette, and Jacob**:

The Examiner has rejected Applicant's claims 299 and 300 over ADPA, Stanton, Rivette, and Jacob (US Patent No. 3,885,566). In making this rejection the Examiner relies upon ADPA, Stanton, Rivette, for the reasons previously stated, and adds Jacob for teaching the printing of novel printed product safety information.

It must be recognized that while the Examiner rejects claims 299 and 300 over ADPA, Staton, Rivetta, and Jacob - Jacob mentions only "warnings." Jacob fails to teach printed product warning information in conjuction with a "proprietary method of use." However, Applicant's claims expressly require as a stated limitation that "the use further comprises..." . Simply placing a warning as does Jacob does not teach creating "proprietary methods of use wherein the use comprises providing printed product warning information ... "

For the above-stated reasons, ADPA, Stanton, Rivette, fail to disclose, suggest or render Applicant's claim 250 or any claim dependent thereon obvious. As a result, simply adding printing of novel printed product safety information to a product or device still leaves one of ordinary skill in the art unable to determine an "essential" adverse event or to act with a method of use "responsive" to such a new essential adverse event. As such none of the cited references, including Jacob, alone or combined, suggest a database of "proprietary essential adverse events." Hence, even if combined, deficiencies remain, and at least one critical element of Applicant's invention cannot be provided by the cited prior art. It is respectfully asserted, therefore, that the rejection of Applicant's claims under 35 U.S.C. §103(a) over ADPA, Stanton, Rivette and Jacob is improper and should be reversed.

Applicant's Response to Examiner's Arguments

The presently cited prior art references cited in the August 31, 2007 Office Action have been maintained over several Actions, and as would be expected, many of the Examiner's arguments have also been maintained. As can be seen from the prosecution history, Applicant and the Examiner remain at odds over the meaning of each cited reference, the motivation to combine them in the manner proposed, and whether a combination would teach every element of Applicants' claimed invention. Moreover, the Examiner has discounted the points made in the Classen Declaration, attached hereto, by Dr. John Barthelow Classen.

The Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966), focused on the procedural and evidentiary processes in reaching a conclusion under section 103. As adapted to ex parte procedure, Graham is interpreted as continuing to place the "burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103." *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984) (In proceedings before the Patent and Trademark Office, the examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art.) The examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Only after the case of obviousness has been established, does the burden of going forward shift to the Applicant.

For a §103 rejection of a patent claim to be valid, the three criteria set forth below must be met: First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

To permit applicant's to rebut assertions of §103 obviousness, the courts have established recognized secondary considerations for responding to an obviousness rejection: (1) evidence of unexpected or nonobvious properties or advantages as compared with the closest prior art; and (2) evidence of real world activities, such as commercial success of the invention or providing a solution to a long-felt need in the art. Condition (1) may be met by either evidence of advantages or unexpected results produced by the invention, or by affidavit or declaration under 37 C.F.R. 1.132. Accordingly, Applicant provides evidence in the attached sworn Declaration of Dr. John B. Classen under 35 U.S.C. §1.132, which demonstrates the ultimate evidence of nonobvious, by offering real world evidence of copying and infringement of Applicant's claimed invention by another, and evidence of that third party's commercial success using Applicant's invention despite expressed skepticism by experts. When combined, these demonstrated secondary considerations clearly demonstrate that, contrary to the Examiner's conclusions, Applicant's invention was not, and is not, obvious over the cited prior art.

Accordingly, if the statements of law or scientific fact, including the Declaration of an expert in the field, are found unpersuasive by the Examiner, then no argument made in Response to the Examiner's comments will move this case forward, and intervention and interpretation by the Board of Appeals is required to move this claimed invention to allowance.

Conclusion

Thus, in light of the foregoing, the prior art fails to render Applicant's invention obvious, and Applicant respectfully requests that, in light of the foregoing, the rejection of Applicant's claims under 35 USC §103 (a) be reconsidered and request that the Board reverse the rejection.

In sum, Applicant requests, therefore, that all rejections be reconsidered and reversed by the Board for the reasons herein stated, and Applicant asserts that all pending claims are in condition for allowance, and respectfully request that allowance be granted at the earliest date possible. No additional fee is believed to be due in this filing. However, if a fee is due, the Office is authorized to withdraw the necessary amount from Deposit Account 50-2424. Should the Board have any questions prior to oral hearing, it is encouraged to contact Applicant's undersigned representative at (215) 772-7550.

Respectfully submitted,

Dated: March 27, 2008 By: Evelyn H. McConathy

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VIII. CLAIMS APPENDIX

As Amended in the Previous Response dated August 13, 2007

Claims 1 – 249 (Canceled)

250. (Previously Presented) A proprietary method of use for a product of manufacture or device, wherein the use was established according to the steps comprising:

accessing one or more data sources, wherein at least one data source comprises adverse event data;

analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device;

identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, and then responsive to identifying of the essential adverse event, identifying the at least one previously unreported method of use for the product or device;

documenting inventorship of the at least one method of use for the product or device; and

creating a database of proprietary essential adverse event information, the database storing data regarding the at least one essential adverse event, wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, and

wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof.

251. (Previously Presented) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprise determining value of commercializing the at least one use determined from the at least one identified essential adverse event.

252. (Previously Presented) The proprietary method of use of claim 251, wherein the steps of establishing the use further comprise commercializing the at least one use.

253. (Previously Presented) The proprietary method of use of claim 252, where in the steps of establishing the use, the commercializing step further comprises generating information for incorporation into documents for selling, leasing or licensing the identified product information.

254. (Previously Presented) The proprietary method of use of claim 252, wherein the product is commercially available at the time of the analyzing step.

255. (Previously Presented) The proprietary method of use of claim 252, where in the steps of establishing the use, commercializing further comprises formatting the data relating to at least one adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one adverse event associated with exposure to or use of the product or device.

256. (Previously Presented) The proprietary method of use of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and where in the steps of establishing the use, the at least one data source comprises information relating to patents and patent applications.

257. (Previously Presented) The proprietary method of use of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and where in the steps of establishing the use, the at least one data source comprises information relating to raw commercial or sales data.

258. (Previously Presented) The proprietary method of use of claim 252, where in the steps of establishing the use, the at least one adverse event comprises a drug interaction.

259. (Previously Presented) The proprietary method of use of claim 258, where in the steps of establishing the use, the at least one data source comprises information relating to raw commercial or sales data.

260. (Previously Presented) The proprietary method of use of claim 250, wherein the steps of establishing the use of the essential adverse event data are proprietary.

261. (Previously Presented) The proprietary method of use of claim 250, wherein the product is medical.

262. (Previously Presented) The proprietary method of use of claim 252, wherein the product is medical.

263. (Previously Presented) The proprietary method of use of claim 262, wherein the medical product is a generic drug.

264. (Previously Presented) The proprietary method of use of claim 250, wherein the product is non-medical.

265. (Previously Presented) The proprietary method of use of claim 252, wherein the product is non-medical.

266. (Previously Presented) The proprietary method of use of claim 250, wherein the device is medical.

267. (Previously Presented) The proprietary method of use of claim 252, wherein the device is medical.

268. (Previously Presented) The proprietary method of use of claim 250, wherein the device is non-medical.

269. (Previously Presented) The proprietary method of use of claim 252, wherein the device is non-medical.

270. (Previously Presented) A proprietary kit containing a product or device, and labeling notifying a user of at least one previously unreported essential adverse event for the product or device, wherein the kit is used in accordance with the proprietary method of use of claim 250.

271. (Previously Presented) A proprietary kit containing a product or device, and labeling notifying a user of at least one previously unreported essential adverse event for the product or device, wherein the kit is used in accordance with the proprietary method of use of claim 259.

272. (Previously Presented) The proprietary method of use of claim 250, wherein the method of use is a restricted use in at least one population subgroup when there is

observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

273. (Previously Presented) The proprietary method of use of claim 253, wherein the method of use is a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

274. (Previously Presented) The proprietary method of use of claim 250, wherein the at least one adverse event is a drug interaction.

275. (Previously Presented) The proprietary method of use of claim 274, wherein the product or device is commercially available at the time of the analyzing step.

276. (Previously Presented) The proprietary method of use of claim 275, wherein the proprietary method of use comprises a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

277. (Previously Presented) The proprietary method of use of claim 275, wherein at least one data source comprises information relating to raw commercial or sales data.

278. (Previously Presented) The proprietary method of use of claim 277, wherein at least one previously unreported essential adverse event is other than a chronic immune mediated disorder.

279. (Previously Presented) The proprietary method of use of claim 277, the steps further comprising determining value of commercializing the at least one proprietary method of use determined from the at least one identified essential adverse event.

280. (Previously Presented) The proprietary method of use of claim 278, the steps further comprising commercializing the at least one proprietary method of use and the product or device is commercially available, wherein commercializing comprises formatting the data relating to at least one previously unreported essential adverse event, such that a manufacturer or distributor of the product or device must inform users about at least one previously unreported essential adverse event.

281. (Previously Presented) The proprietary method of use of claim 250, wherein at least one previously unreported essential adverse event comprises a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data.

282. (Previously Presented) The proprietary method of use of claim 252, wherein at least one previously unreported essential adverse event comprises a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data.

283. (Previously Presented) The proprietary method of use of claim 250, wherein the at least one adverse event data source comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

284. (Previously Presented) The proprietary method of use of claim 250, wherein the at least one adverse event data source comprises information regarding amount of use of the product or device or duration of exposure to the product or device by subjects.

285. (Previously Presented) The proprietary method of use of 250, wherein the at least one method of use of the product or device is a restricted use in at least one population subgroup, where there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the previously unreported essential adverse event is one other than a chronic immune mediated disorder.

286. (Previously Presented) The proprietary method of use of 252, wherein the at least one method of use of the product or device is a restricted use in at least one population subgroup, where there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the previously unreported essential adverse event is one other than a chronic immune mediated disorder.

287. (Previously Presented) The proprietary method of use of claim 250, wherein the product or device is commercially available, the steps further comprising identifying the method of use as a restricted use in at least one population subgroup when there is

observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

288. (Previously Presented) The proprietary method of use of claim 251, wherein the product or device is commercially available, the steps further comprising identifying the method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

289. (Previously Presented) The proprietary method of use of claim 252, wherein the product or device is commercially available, the steps further comprising identifying the method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

290. (Previously Presented) The proprietary method of use of claim 259, wherein the product or device is commercially available, the steps further comprising identifying the method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

291. (Previously Presented) The proprietary method of use of claim 250, the steps further comprising documenting date of inventorship.

292. (Previously Presented) The proprietary method of use of claim 250, wherein at least one adverse event data source comprises raw data from a plurality of different adverse events.

293. (Previously Presented) The proprietary method of use of claim 250, wherein the product or device is commercially available, and the method of use is further identified as comprising restricting exposure of the product or device to at least one factor selected from the group consisting of high temperatures, low temperatures, chemicals, surfaces, pressures, electricity sparks; contact with an anatomical element selected from the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the user; exposure to a subpopulation group selected from the group consisting of children, pregnant women, users with specific allergies, users with specific

medical conditions, and animals; exposure to subpopulations defined by at least one user-identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, use of drugs, use of tobacco, use of alcohol, and use of medical devices.

294. (Previously Presented) The proprietary method of use of claim 250, wherein at least one database of essential adverse event information is computerized.

295. (Previously Presented) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprises accessing one or more data sources, wherein at least one data source comprises human adverse event data.

296. (Previously Presented) The proprietary method of use of claim 250, wherein the steps of establishing the use further comprises utilizing least one controlled clinical trial and or epidemiological study to discover at least one previously unreported essential adverse event.

297. (Previously Presented) The proprietary method of use of claim 250, wherein the step of establishing the adverse event is one other than an abnormal laboratory value.

298. (Previously Presented) The proprietary method of use of claim 250, wherein the use is one other than a new dosing regimen.

299. (Previously Presented) The proprietary method of use of claim 250, wherein the use further comprises providing printed product safety information in connection with product packaging.

300. (Previously Presented) The proprietary method of use of claim 252, wherein the use further comprises providing printed product warning information in connection with product packaging.

IX. EVIDENCE APPENDIX

TAB 1. Declaration of John Barthelow Classen, M.D. ("Classen Declaration") signed on March 29, 2007 and entered into the prosecution record under 37 C.F.R. §1.132 on March 29, 2007.

TAB 2. Pub. No. 2002/0039990 (Stanton) as cited by the Examiner.

TAB 3. US Patent No. 5,991,751 (Rivette) as cited by the Examiner.

TAB 4. US Patent No. 6,458,958 (D'Ambra) as cited by the Examiner.

TAB 5. US Patent No. 5,678,234 (Colombo) as cited by the Examiner.

TAB 6. US Patent No. 6,018,714 (Risen) as cited by the Examiner.

TAB 7. US Patent No. 3,885,566 (Jacob) as cited by the Examiner.

X. RELATED PROCEEDINGS APPENDIX

The inventor, the respective Assignee (Classen Immunotherapies), and Assignee's collective undersigned legal representative are unaware of any appeals or interferences that are related to the instant appeal, or that will affect, be affected by or have any bearing on the Board's decision in the instant appeal.

AUTHORIZATION

Applicant believes that no additional fees or extension of time are required for this submission. However, in the event that an extension of time is required, Applicant hereby submits a petition for such extension of time as may be necessary to make this response timely. The Commissioner is hereby authorized to charge any necessary fees to deposit account No. 50-2424. A duplicate of this Authorization is enclosed.

Respectfully submitted,
Classen *et al.*

Dated: March 27, 2008

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EHM:tmf

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John Barthelow Classen

Application No.: 10/081,705 **Art Unit: 1273**

Filing Date: 02/21/2002 **Examiner: Etienne LeRoux**

Title: Computer Algorithms and Methods for Product Safety

DECLARATION OF JOHN BARTHELOW CLASSEN UNDER 37 C.F.R. §1.1.32

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

I, JOHN B. CLASSEN, do declare and state that:

1. I am a physician scientist and the inventor of the patent application under review as well as U.S. Patent Nos. 6,219,674 and 6,584,472. I am also President and CEO of Classen Immunotherapies Inc. In addition, I am the inventor on a number of other patents relating to vaccine safety, including U.S. Patent Nos. 5,723,283; 5,728,385; 6,420,139; 6,638,739; and 7,008,790. My curriculum vita is available to the Examiner upon request. On several occasions I have provided expert testimony on vaccine safety to the Congress of the United States.

2. I have extensively researched the performance of scientists and events in the pharmaceutical industry, and the industry itself, and to the best of my knowledge before my invention, those in the industry believed that generic drug competition was inevitable once patents expired claiming a composition of matter, a first therapeutic use of the composition, and/or a method of its manufacture, and that there was no legal way of stopping generic competition, except through specific legislation from Congress.

Furthermore, it was the accepted wisdom of the industry that there was no positive value to be gained from discovering adverse events or warning consumers about such adverse events. Prior to my invention, those in the industry had demonstrated no way to commercialize or profit from warning people about any risk(s) associated with using a product.

3. My invention revolutionized the pharmaceutical industry in that now, those, who have learned of my teachings, know that it is possible to completely inhibit generic drug competition by continually finding new adverse events resulting from the use of a product, and patenting the disclosure of these adverse events. I have been asked to give presentations, including these findings at three meetings held by the Center for Business Intelligence, and I have also given presentations to many pharmaceutical companies, including GlaxoSmithKline, Johnson and Johnson, AstraZeneca, Aventis, Taro, Supernus, MedPointe, Cypress Bioscience and others. It is my belief that my technology is being used, without my permission, at least by Elan Pharmaceuticals, Inc., King Pharmaceuticals, Inc., and Mutual Pharmaceutical Company. See, Civil Action No.: 1-04-CV-03521 WDQ), *Classen Immunotherapies, Inc. v. King Pharmaceuticals, Inc., et al.* My invention has been the subject of interest to the lay press (**Exhibit A**) and discussed by the U.S. Senate (**Exhibit B**).

4. I believe that my interaction with Elan Pharmaceuticals, is evidence of non-obviousness of my invention, demonstrating unexpectedness and superiority of outcome over the prior art, evidence of commercial success, and evidence of copying. In particular, Elan's use of the technology shows that they could have prevented generic competition, but did not believe it was possible until after hearing my presentation in 2001. If, prior to 1999, Elan had known that it was possible to prevent generic drug competition to their existing products (Skelaxin and Zanaflex) for their existing indications (muscle relaxants), then Elan would not have waited so long (until November 2001) before seeking new patents. Had they not delayed, Elan would not have lost their lead product, Zanaflex, to generic drug competitors. There was a wealth of safety data available that Elan could have found, inexpensively and quickly, but they did not know what information to look for and how to commercialize that data.

5. I spoke with two Elan employees, Nancy Santilli and Cara Pellegrini, when the attended my presentation at the Center for Business Intelligence meeting, November 15-16, 2001. **(Exhibit C)**. Both were involved with Elan's muscle relaxant business, which included Skelaxin and Zanaflex. Neither drug was protected by a patent, and each drug faced imminent competition from generic drug manufacturing companies. Ms. Pellegrini was at the time assigned to obtain business intelligence for Elan and to bring new technologies to the company. After hearing my talk and receiving copies of my patents, these individuals returned to Elan and talked with the company's patent attorney.

6. Within weeks of meeting with me, Cara Pellegrini filed a patent application claiming a drug/food interaction on Zanaflex (now U.S. Patent No. 6,455,557, filed November 28, 2001), and her co-worker filed a patent application claiming a drug/food interaction on metaxalone (now U.S. Patent Nos. 6,407,128 and 6,683,102, filed December 3, 2001). The '102 patent is, in fact, the subject of my patent infringement suit with Elan. The Elan patents cover an adverse event, i.e., a drug/food interaction (drug interaction), that is specifically covered by my '674 patent (claims 28, 57, 82). While Elan relied heavily on the income from these two muscle relaxants (approximately $400 million dollars for the year 2005), generic drug competition was an imminent threat. Nevertheless, Elan failed to file patent protection for the drug/food interaction until weeks after hearing me present the method claimed in my patent. In fact, Elan already had the data on the drug/food interactions in their database, but they did not screen the database to uncover the patentable information until after learning of the technique for doing so from my presentation of my invention.

7. Within weeks of filing the subject patent applications for Zanaflex and Skelaxin, I was contacted by Steve Cartt, the director of Elan's muscle relaxant division. He said that both Nancy Santilli and Cara Pellegrini reported to him, and that Elan was interested in licensing the technology in the '674 and '472 patents. On January 4, 2002 Cartt told me that he believed my technology would be of great value to Elan and that they wanted my help for using my technology to generate more patents for Elan. Cartt then arranged a conference call on January 11, 2002 with Elan's chief patent attorney, Jean Duvall, during which we discussed my patents. After the conference call, I was told

that Elan wanted to continue to work with me to strengthen their patent portfolio, and they asked me to submit an document to begin exploring possible licensing arrangements. Elan continued to ask me to provide help to them for strengthening their patent portfolio. A series of e-mails ensued (**Exhibit D**).

8. Before Elan was issued patents on either of the drug/food interactions, a generic drug competitor of Zanaflex entered the market, Elan's sales dwindled and Elan lost interest in the product. However, Elan's patent on informing patients about a drug/food effect with Skelaxin was issued before the generic drug competitors entered the market. Elan and its partner King Pharmaceutical changed the labeling to include information on drug-food interactions and have kept generic drug competitors off the market by arguing that competitors must disclose the patented safety information. However competitors are blocked from disclosing the necessary safety information because of the patents. To date, there is no generic drug competitor in the market, despite the fact that the FDA approved a generic product, and generic drug manufacturers have tried to enter the market. The product sells about $400 million a year, or about $100 million a quarter (**Exhibit E**). More recently, generic drug competitors have begun copying my technique in the hope of forcing Elan and King to cross-license the patents based on claims relating to the discovered drug/food interaction. Mutual Pharmaceutical Company, a generic manufacturer, has received its own patent (US Patent No. 7,122,566, **Exhibit F**) resulting from an identified drug/food interaction.

9. During my many interactions with Elan, often initiated by Elan, they never said, suggested or implied that they believed my patents were anything but valid, and they never indicated that my inventions were not novel. In fact, Steve Cartt, who worked closely with the chief patent attorney, Jean Duvall, praised me for my help and the originality and usefulness of my technology. Regardless of what they may now say in this proceeding, I believe Elan's actions demonstrate that my invention is novel and that the methods were non-obvious. If the patent decision-makers at Elan had thought my patents were obvious as they now suggest in their Request for Reexamination, why would they continue to hold discussions with me for 6 months and continually ask me for help? In fact, Elan's own actions by its officers and employees are proof that, at the filing date, my technology was not obvious to those skilled in the art.

10. Elan's behavior cannot be ignored, and the secondary considerations demonstrated by Elan in 2001 and 2002 with regard to my technology, demonstrate that others in the art also believed it to be non-obvious. Moreover, it shows that my invention offered unexpected results in the art, along with a method for blocking competition from generic drug manufacturers. It also shows that one can create tremendous value from warning consumers about adverse risks of using a product. Neither my method for blocking competition or for creating value from a finding of an adverse event had been accomplished or proposed in the art prior to my invention. In addition, the 2001 and 2002 response by Elan upon learning of my invention, demonstrates by all 5 recognized, secondary consideration criteria for establishing non-obviousness of an invention in view of the prior art. This evidence relates to the real world activities of others, and indicates what one of ordinary skill in the art would or would not have done.

(a) *Commercial success of the claimed invention*: From my invention Elan learned to scan their databases to detect patentable information that will permit them to keep competitive generic drugs off the market. Elan did not file patents on this information until after they had met with me. Despite the fact that they had the data available in their databases, and they knew that something had to be done to prevent generic drug competition, they did not know how to find the valuable data until they met with me. However, once Elan was taught my invention, they learned how to quickly and efficiently search and find valuable data to prevent generic drug competition.

(b) *Long felt need in the art for a solution to a recognized problem*: It was, and continues to be, well-known in the art, that generic drug competition will develop as soon as the original composition of matter, first therapeutic use, and sometimes, method of manufacturing patents expire for a successful and profitable drug. Consequently, companies have looked for all sorts of ways to inhibit generic competition. Moreover, there was a need to stimulate companies to look for and disclose risks associated with their products.

(c) *Failure of others to solve a known problem*: There have been numerous attempts by others to block generic drug competition, but they have failed to prevent generic drug competition of the first therapeutic use. Also,

finding adverse events has made headlines in recent years, and there is a consensus in the art that such adverse events should have been detected as soon as possible. Yet, there was little incentive for manufacturers to invest heavily in finding out about the risks associated with the use of their products. Conversely, there is a significant incentive for finding new drug indications.

(d) *Skepticism of experts*: It was believed at the filing date of my '674 patent that it was not possible to completely prevent generic drug competition for the original formulation and original indication of a compound after the original patents had expired.

(e) *Copying of the invention in preference to the prior art*: In the actions described above, it is clear to me that Mutual Pharmaceuticals Co. copied my invention and obtained their own patent on a drug-drug indication involving a pre-existing compound.

11. In summary, I believe that, at least, the above-described actions by Elan and by Mutual Pharmaceuticals prove that my inventions were not obvious.

12. I declare that adverse events are not equivalent to outcome studies or their results. Outcome studies most often relate to efficacy.

I hereby declare further that all statements made herein of my own knowledge are true and that all statements on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the captioned patent.

Date: March 29, 2007

John Barthelow Classen

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Running with the Hare, Hunting with the Hounds

2 May 2001

When a company claims that its new patented system is expected to have 'a major impact' on the pharmaceutical and chemical industries, one is inclined to sit up and pay attention. Baltimore based Classen Immunotherapies has just been issued US patent number 6,219,674 for a 'business method' which leads to the inhibition of generic products by patenting the disclosure of new adverse event information.

The key to the Classen claim is that a manufacturer of a product, which continues to discover new adverse events associated with that product can 'patent the disclosure of this new adverse event information and thereby prevent generic competition indefinitely'.

Classen continues: 'Even in situations where a regulatory agency such as the FDA is unwilling to force a generic product with inadequate warnings off the market, courts of law have stepped in and taken harsh actions against companies for failing to warn about adverse events. Manufacturers who continue to perform inadequate safety testing of their products could lose exclusivity of their products long before the original patent on their product expires.'

After a struggle to understand this patent, we spoke to Bart Classen and he explained it thus: "Yes, it is a business method, which amongst other things, screens for new adverse events in drug interactions. If, for example, a drug is about to go off patent, you can find a new use for it, for example in a way which makes it safer, and take out a patent." This prevents imitators from manufacturing competitive generic versions.

If a generic competitor licenses the new business method patent from Classen, or discovers and patents a new adverse event associated with a brand name product, this generic competitor can then force the original manufacturer to remove the product from the market or demand from the manufacturer a license to manufacture the product.

So we asked Bart Classen if he was selling generic competitors a device for competing with leading manufacturers. Or threatening to sell such a device if the principles did not buy it first?

He replied: "We are offering two things: to help manufacturers

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maintain their monopoly, and to protect them from pirates. They can always say 'Screw the pirates — we'll get them in court!'"

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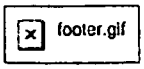

Press Release

FOR IMMEDIATE RELEASE: April 23, 2002

SCHUMER: DRUG COMPANIES STOOPING TO NEW LOW BY SEEKING PATENTS ON SAFETY INFO

Senator says patent abuses are costing consumers, businesses, and insurers millions

Schumer presses GAAP legislation that would reform Hatch-Waxman to ensure that low-cost drugs inject a needed dose of competition into the drug industry

US Senator Charles E. Schumer, co-author of the Greater Access to Pharmaceuticals (or GAAP) Act, offered testified at the Senate Commerce Committee Hearing on Generic Pharmaceuticals: Marketplace Access and Consumer Issues. Schumer spoke about a new tactic that the name-brand pharmaceutical companies are using to block the entry of low-cost, generic drugs that involves seeking patents on information related to safety. The FDA has long determined that safety information is part of the public domain.

Schumer pointed to the example of the pain medication, Ultram. Although five generic versions of it were about to be approved in January of this year, its producer, Ortho McNeill, filed a patent on a slightly altered dosing schedule, a schedule which is obvious to most pharmacists, but one which they claim is essential to the safety of the drug. Under Hatch-Waxman, patenting this information would at the very least automatically keep the generic off the market for 30 months. If the patent is upheld in the courts, it would prevent competition until 2019. With sales of over $690 million per year, these delays will cost consumers over $3 million per week. Schumer made the following statement at the hearing:

"I would first like to thank Chairman Hollings for scheduling a hearing on such an important issue, as well as Senator Dorgan and Senator McCain, for chairing the hearing today. I thank you both not only for your long-term commitment to finding a solution to bringing drug costs down for our consumers and seniors – but also for taking this crucial first step of holding a hearing on Hatch-Waxman reform and the GAAP Act – the bill that Senator McCain and I have introduced to ensure timely access to affordable pharmaceuticals.

"An ad in the Washington Post yesterday paid for by PhRMA reported that 75% of physicians agreed that patent laws are very important to the future of America's medicines. Well, I'm not a doctor, much to the chagrin of my mother, but I couldn't agree more. Continued innovation in pharmaceutical development is key to ensuring that patients have access to life-saving drugs when they need them.

"But the PhRMA ad only tells part of the story. It implies that patent laws were put in place to benefit consumers solely by protecting innovation. There's a flip side. Our patent laws aren't just meant to stimulate innovation. They're also intended to bring scientific knowledge into the public domain – to eventually spur competition and to keep the drug companies from holding a never-ending monopoly over the heads of consumers.

"But in the world of the drug industry right now, the brand companies are extending their monopolies to the detriment of consumers. There are a number of loopholes in the patent laws which drug companies exploit every day to block their low-cost competitors from breaking into the marketplace. Take, for example, Paxil, a drug with $2.1 billion in sales used to treat obsessive-compulsive disorder.

"Glaxo SmithKline sued the first generic applicant, Apotex, in 1998 over a patent intended to expire in 2006. This move automatically delayed competition for 30 months, and has continued to prevent competition while the litigation is ongoing.

"Even if the companies come to resolution on this first patent, Glaxo has listed nine additional patents on the drug in the intervening years since the first lawsuit began – patents on slightly different chemical substances (which have never been approved for marketing by the FDA, but which the company claims are relevant to Paxil), as well as patents on different formulations of the drug. The last of these patents expires in 2018. Most of these new patents will– and already have – invoked additional, multiple 30-month stays against generic competition for Paxil. Each year generic competition is delayed may cost consumers up to $500 million.

"What happened here is that the drug company saw its original patents about to expire and then created new ones to maintain its control over the market. These kinds of practices have become the norm in the drug industry. These companies figure out a new way to keep the dollars rolling in, stooping to new low every day to maintain their exclusivity rights.

"I have recently learned of the latest low to which the big pharmaceutical companies are stooping to block the entry of low-cost, generic drugs. They have begun to seek patents on information related to safety. The FDA has long determined that safety information should be part of the public domain and that it shouldn't prevent generic versions of approved drugs from coming to market.

"In the case of the pain medication, Ultram, five generic versions of it were about to be approved in January of this year. But in February, Ortho McNeill filed a patent on a slightly altered dosing schedule, a schedule which is obvious to most pharmacists, but one which they claim is essential to the safety of the drug.

"Under Hatch-Waxman, patenting this information would at the very least automatically keep the generic off the market for 30 months. If the patent is upheld in the courts, it would prevent competition until 2019. With sales of over $690 million per year, these delays will cost consumers over $3 million per week.

"Prescription drug expenditures are throwing insurers, corporations, and state Medicaid agencies into a tailspin, as they attempt to craft high quality health care benefits that are within the realm of affordability. They're crippling consumers and seniors who can't afford to purchase their drugs or take them every day as prescribed.

"I agree that patent protection is key to saving lives, but I'm sure the doctors surveyed by PhRMA would also agree that a drug can do no good if it is financially out of the reach of patients who depend on it.

"So, with this in mind, I want it to be clear about what this hearing is NOT about. It's not about robbing pharmaceutical companies of legitimate patent protection, it's not about theft of innovation, it's not about taking steps to enact laws that are NOT in the best interest of consumers.

"In fact, it's about just the opposite. It's about examining competition in today's marketplace and revisiting a compromise which was struck nearly 18 years ago.

"In 1984, Congress passed one of the most important and least appreciated pro-consumer laws of the past 2 decades. Hatch-Waxman provided additional patent protection for research-based brand name drugs and created a mechanism to allow less expensive generic equivalents on to the market.

"Hatch-Waxman has saved consumers billions of dollars on pharmaceuticals while helping brand name companies stay profitable and innovative.

"Generic drugs have captured over 44% of the market in terms of number of prescriptions written, and pharmaceutical research and development has increased nearly seven-fold from $4.1 billion in 1985 to $26.4 billion in 2001. The pharmaceutical industry once again topped the Fortune 500 list of most profitable industries.

"But, in recent years, as the profits and stakes have become higher, drug industry lawyers have picked the Hatch-Waxman law clean. Companies are aggressively pursuing extended monopolies through filing weak or invalid patents and engaging in deals which the FTC is increasingly scrutinizing for anti-competitive motives. We must put an end to these abuses.

"Prozac, a blockbuster drug which enjoyed $2.4 billion in revenue in 2001, finally came off patent last August. Since then prices have dropped more than 90%, and estimates indicate that nearly 80% of former Prozac consumers are now using the generic.

"According to these estimates, generic competition for Prozac will save consumers over $1.8 billion this year alone. That is just one drug. With potential savings this significant, Congress has a responsibility to ensure that Hatch-Waxman is working the way it was intended.

"The bill Senator McCain and I have introduced – the Greater Access to Pharmaceuticals (or GAAP) Act seeks to breathe new life into Hatch-Waxman, not by redrawing ideological battle lines, but by restoring the intent of our patent laws. Our intention is not to cut innovators off at the knees and it isn't a freebie for the generic drug industry. It is a pro-consumer bill that restores the balance intended by Hatch-Waxman.

"The bill would eliminate the automatic 30-month stay handed to brand companies who file suit against a generic challenger. It would instead require these companies to allow a court to decide whether their case merits a stay.

"It would prevent abuses like the Paxil and Ultram examples by reducing incentives to list patents that are not truly innovative, but instead are intended solely to extend monopolies.

"The GAAP Act reforms the so-called "180-day rule" by closing the loophole that enables a brand name company to pay a generic manufacturer to stay off the market, effectively putting the kibosh on competition. Closing this loophole would prevent problems like the cases we're discussing here today– the Hytrin case

where Abbott Laboratories allegedly paid Geneva Pharmaceuticals $4.5 million per month to keep their hypertension drug off the market.

"Or the K-Dur 20 case, recently settled by the FTC, in which Schering Plough allegedly paid Upsher-Smith and American Home Products millions of dollars to delay launching a generic potassium chloride supplement.

"Mr. Chairman, as Congress wrestles with the complexity of crafting and paying for a Medicare prescription drug benefit, we must not overlook a straightforward solution to the escalating drug prices facing seniors, businesses, insurers and consumers today.

"If we can ensure fair competition in the pharmaceutical marketplace – a level playing field for both brand and generic companies – then everyone will win.

"I thank you, Mr. Chairman, for holding this important hearing today and look forward to working with you, with Senator McCain, and with the FDA and the FTC to encourage fair marketplace practices – while preserving both safety and intellectual property rights – to provide customers with affordable pharmaceutical alternatives."

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Classen MD MBA

Classen Immunotherapies Inc

The Center for Business Intelligence, LLC

Badges must be worn at all times. registration is non-transferrable SP WS:

Pharmaceutical Product Lifecycle Strategies

Nancy
Santilli

Elan Corp

The Center for Business Intelligence, LLC

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Pharmaceutical Product Lifecycle Strategies

Tony
Gross

GlaxoSmithKline

The Center for Business Intelligence, LLC

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Pharmaceutical Product Lifecycle Strategies

John
Wiedemann

AstraZeneca

The Center for Business Intelligence, LLC

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Choose from Two Pre-Conference Workshops: Thursday, Nov

Workshop A: Identify Rx-to-OTC Switch Strategies Early

Pressure to increase profits and deliver shareholder value, coupled with patent expirations, aggressive generic competition and rising costs, necessitate increasing attention to lifecycle management as a vehicle to maximize return on investment. Rx-to-OTC switch is increasingly recognized as more than a strategy of last resort. Proactive switch planning, as part of a total lifecycle plan, can open the door to incremental growth opportunities prior to patent expiration and to the creation of switch strategies capable of maximizing total corporate NPV.

Through industry examples and case studies, this workshop makes the case for assessing switch opportunities early in a drug's patent life and offers guidelines for evaluating switch feasibility and success metrics, identifying and assessing alternate entry strategies and identifying collaborative approaches to maximize success.

7:30 *Workshop Registration*

8:30 *Workshop Leader's Welcome and Opening Remarks*

I. **The Business Case for Early Switch**
- Success stories from industry
- The threat from FDA — The non-scheduling and inability case study

II. **How to Assess Switch Feasibility**
- When to begin feasibility assessment
- Key criteria in switch assessment

III. **How to Evaluate the Financial Implications of Alternate Entry Strategies**
- Identify the products and indications most likely to make money
- Reduce the risk of cannibalization
- Determine optimal switch timing
- Develop a post-switch lifecycle plan
- Develop credible forecasts

IV. **Build a Team to Support Corporate ROI Goals**
- Criteria for determining a team's make up
- Goal setting and success metrics
- Avoid the common pitfalls of OTC marketing partnership
- Structure internal incentives to ensure company-wide commitment
- Checkpoints to evaluate success

Workshop B: Manage Intellectual Property to Increase S
Financial Models and Analysis to Support Deci

As industry more carefully examines which drugs merit further investment and which to let go, this workshop offers guidance on where to dedicate time and resources to ensure greater profits. Global patent wars illustrate the value of comprehensive patent planning. The objective of a strategic intellectual property plan is simple: nurture, maximize, maintain and protect the value of the enterprise's intellectual property. Our workshop focuses on a "Modified Eight Step Lehman Plan," created toward patents and named after the former Commissioner of the U.S. Patent and Trademark Office and advocate of a substantial portion of this plan. Learn to value intellectual property and business patents to engage in partnerships and business decisions that ensure financial success.

7:30 *Workshop Registration*

8:30 *Workshop Leader's Welcome and Opening Remarks*

I. **Conduct an IP Audit**
- Identify actions that need to be taken with respect to:
  - existing patents, patent applications and inventions for which applications need to be prepared and prosecuted

II. **Create and Maintain Invention Discovery Management Protocols**
- Systematically identify and track the enterprise's intellectual property

III. **Formulate and Implement a Patent Strategy**
- Formulate and implement a patent strategy consisting of a series of patents with claims of varying scope that (borrowing from the Rivette/Klein "IP-3" model) protect core technology, reinforce core patents and control process choke points

IV. **Develop an Invention Disclosure Program for Non-Trade Secret Inventions Not Chosen for Patents**
- Publicly establish priority of inventions as a defensive move with respect to inventions for which neither patent nor trade secret protection will be sought

V. **Police and Enforce Intellectual Property**
- Identify infringements by third parties
- Periodically review trade press and competitors' marketing materials and regulatory filings for signs of infringement
- Implement procedures for handling reports of alleged infringement and sending standard cease and desist notices to infringers and litigate when necessary

VI. **Defend Against Claims of Infringement**
- Defend the enterprise against claims of infringement by third parties

VII. **Portfolio Maintenance and Growth**
- Adopt the Rivette/Klein "Grow-Fix-Sell (License)" patent cycle model

VIII. **Valuation of Patents**
- Understand different methods of valuing patents for purposes of making grow (fix-sell (license) decisions using econometric valuation methods that focus on aggregate statistics
- Legislative approaches that endeavor to balance political issues courts use the Georgia-Pacific factors to set license fees

To Register Call Toll Free 800-817-8601 (781

Register by September 7, 2001 and Save $200 on this First-Ever Forum!

Optimize Revenue Streams and Increase Profitability through

Pharmaceutical Product Lifecycle Strategies

November 15-16, 2001 • Capital Hilton • Washington, D.C.

Choose from Two Pre-Conference Workshops – Thursday, November 15, 2001

A: Identify Rx-to-OTC Switch Strategies Early In a Drug's Patent Life

- Evaluate switch feasibility
- Assess alternate entry strategies
- Identify collaborative approaches
- Reduce the risk of cannibalization

B: Manage Intellectual Property to Increase Shareholder Value

Financial Models and Analysis to Support Decision Making

- Develop an invention disclosure program
- Adopt the Royalty Kleen "Grow, Fix, Sell" decision model
- Understand new accounting approaches for intangibles
- Learn about the Black-Scholes option pricing model

- Hear Dynamic Presentations and Case Studies on How to:
- ➢ Accelerate product launch success through **patient registry programs**
- ➢ Successfully introduce a **"discontinuous" innovation** to the marketplace
- ➢ Benefit by focusing on **brand strategy** vs. brand management
- ➢ Optimize sales through **customized patient compliance programs**
- ➢ Capitalize on newly discovered options from **Phase IV clinical studies**
- ➢ Form strategic alliances – the critical difference between **co-promotion** and **co-marketing**
- ➢ Leverage **novel drug delivery systems** for patent extension
- ➢ Understand the impact of impending legislative initiatives on **market exclusivity** strategies
- ➢ Gain an appreciation for expectations vs. reality in the **patent extension application process**
- ➢ Use **global patent protection** as part of the lifecycle planning process
- ➢ Profit by **patenting adverse event information** on your products

Produced by: CBI's Pharmaceutical Series

mber 15, 2001

a Drug's Patent Life

1:00 *Close of Workshop*

There will be a 10-minute networking and refreshment break at 10:00 am

About Your Workshop Leader

Susan LaVise Coleman, President, NGI Consulting joined Nelson Consultants in 1990 as Vice President of NGI Consulting and was named President in 1995. Since its creation in 1989, NGI Consulting has become a leader in providing long-term strategic planning, business development and executive plan implementation support to the healthcare industry. Clients include many of the largest U.S. pharmaceutical manufacturers, including Pfizer, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Novartis and Pharmacia. This has led to work in a broad range of therapeutic categories, including respiratory diseases, cardiovascular, metabolics, malignancies, anesthesiology, antivirals, urology, women's health, dermatology and many others. In addition, NGI Consulting has a major sub-practice in DTC, having developed and implemented or having evaluated over 200 television commercials, and having worked on twenty-nine actual launches, in just the last three years. Prior to joining Nelson Consultants, Susan was U.S. Director of Therapeutic Skin Care at Johnson & Johnson, as well as Worldwide Development for adult dermatology prodrugs. Earlier, she led major brand teams in marketing and in oral health products. Susan has a master's degree in Marketing and Finance from the Kellogg School of Management at Northwestern University.

archolder Value — on-Making

- Venture finance models that focus on discounted cash flow models
- New accounting approaches for "intangibles"
- Financial modeling tools like the Black & Scholes option pricing model
- The public equities market - the final arbiter

00 *Close of Workshop*

...ll be a 10-minute networking and refreshment break at 10:00 am

About Your Workshop Leader

...L. Jaklitsch, Esq., Partner, Sidley Austin Brown & Wood joined the firm in ...and was appointed a partner in 1989. He has worked in the venture and ...nology field for over 20 years, with particular emphasis in the life science and ...nation science industries. In the life science industry, Mr. Jaklitsch's experience ...s has been with companies engaged in various aspects of developing and ...nercializing pharmaceuticals, biotechnology and genomics/proteomics ...nology. In the information science industry, Mr. Jaklitsch's experience includes ...panies engaged in various aspects of developing and commercializing computer ...ware and software, communications equipment, networking and interworking ...ware and electronics. Mr. Jaklitsch's assignments encompass private placements and ...ic offerings of equity and debt securities, on underwriters' counsel, investors' ...sel and issuer's counsel; technology licensing and development; strategic ...borations, mergers and acquisitions, and other contractual arrangements by ...panies located in the Americas, Asia and Europe. Securities offerings in which ...Jaklitsch has participated include seed stage, venture and mezzanine round equity ...ancings by start-up and emerging companies, initial public offerings and ...on private and public offerings by public companies. Intellectual property ...s play a key role in many of Mr. Jaklitsch's assignments, particularly with respect ...all forms, drafting of agreements and licenses and preparation of disclosure ...ments, such as private placement memoranda and prospectuses. ...Jaklitsch received a BA in Mathematics from Lehigh University and an MBA and ...Juris Harvard University.

"Drugs with combined 1999 s...

MAIN CONFERENCE

Day One — Thursday, November 15, 2001

12:00 *Main Conference Registration*

1:15 *Chairman's Welcome and Opening Remarks*
Gregory S. Zaiko, Director of Business Development
Alexion Pharmaceuticals, Inc.

1:30 **The Payoff of Customer-Focused Marketing**
- Maximize the fit between the firm's capabilities and customer needs
- Define and profile the "customer"
  - >payors
  - >physicians
  - >patients
- Case example

Ashok D. Pal, Director Global Marketing - Allergy, Pharmaceutical
Alcon Laboratories, Inc.

2:15 **Prepare the Marketplace for Your Product — Engineer an Environment for Success**
Strategic market planning uncovers the greatest points of leverage and addresses inhospitable climates. To assess the marketplace and engineer a climate where your product is poised for success this session covers the following:
- How to introduce a "discontinuous" innovation
  - >what does your target know?
  - >what does your target need to know?
  - >articulate where your product fits within the category
- Understand what it takes to be successful
  - >pre-launch planning
  - >strategic reimbursement
  - >commercial sales
- Ongoing market surveillance
  - >uncover insights
  - >make insights actionable

Claudia Graham, PhD, MPH, Vice President, Marketing and Product Development, MiniMed, Inc.

3:00 *Networking and Refreshment Break*

39-2438 outside the U.S.) or Fax 781-939-2490

es of $100 billion will lose patent protection by 2005?" —Datamonitor

3:15 **Accelerate Product Launch Success through Patient Registry Programs**
- Engage the interest of important audiences in the post-approval, pre-launch phase
  - >physicians, hospitals
- Integrate analysis to improve
  - >payer, physician and patient acceptance
- Utilize enrollment and program summaries as a point-of-entry strategy with
  - >gatekeepers, opinion leaders
- Ethical, privacy and regulatory considerations

Edward J. Doubleday, Senior Vice President, McKesson HBOC Pharmaceutical Partners Group

4:00 **Use Strategic Brand Management to Build Equity for Increased Profitability**
- Creating and managing brands can add layers of value to hard-won and fiercely defended intellectual property.
- Strategic investment in branding holds promise for building connections and affinity by prescribers and patients for branded products to help stave off generic competition and price sensitivity.
- Why the sudden discussion about brands?
- Benefits of focusing on brand strategy vs. brand management tactics
- Value derived

Bob DeBonis, Executive Vice President, Corbett Healthcare Group

5:00 *Close of Day One*

5:00 - 6:00 ***Wine & Cheese Networking Reception***

Join colleagues and friends in a relaxed setting

Day Two — Friday, November 16, 2001

7:30 *Continental Breakfast*

8:00 *Chairman's Review of Day One*
Gregory A. Zadel, Director of Business Development, Alexion Pharmaceuticals, Inc.

8:15 **Optimize Sales through Customized Patient Compliance Programs**
- Application for short- and long-term therapies
  - >lifestyle drugs
  - >disease management
- Appeal to payors, prescribers and patients
- Move the needle for success in terms of patient outcomes and sales
- Implications for insulation against generic and innovator competitors
- Fine-tuning for new drug delivery systems
- Industry case study

Major J. Stryker, PhD, Director, University of Michigan Health Media Research Laboratory

9:00 **Medical/Marketing Strategies for Phase IV Clinical Trials — New Emphasis, Greater Priority**
- Begin with an end in mind — The importance of study design
- Physician and patient targeting
- Identify opportunities through epidemiology
- Evaluate the costs and benefits of alternatives
- Create programs to capitalize on newly discovered options

Gary R. Larson, PhD, Clinical Director, Worldwide Neuroscience, Pfizer

9:45 *Networking and Refreshment Break*

10:15 **Form Strategic Alliances to Support the Lifecycle Plan**
- Criteria for identifying and selecting partners
- Critical differences between co-promotion and co-marketing
- What represents the best option for your product?
- Division of roles and responsibilities
- Incentive structures
- Success metrics
- Case studies

Gregory A. Zadel, Director of Business Development, Alexion Pharmaceuticals, Inc.

11:00 **Improve Product Positioning and Product Enhancement through Novel Delivery Systems and Effective Lifecycle Management**

Drug delivery technology and systems add value beyond simply delivering a drug. They can help improve a pharmaceutical company's product pipeline as well as improve marketing potential, commercialization and even breathe new existence into a product's lifecycle. How do you leverage a drug delivery system to improve marketability and new product positioning?
- Identify when to use a drug delivery product to help position your product
  - >drugs that can benefit
  - >technologies that work well with product enhancement
  - >strategies to incorporate drug delivery into your marketing
  - >does market research really give accurate direction for the use of novel formulations?
- Understand how these deals are structured
- Utilize drug delivery to gain competitive advantage

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- Leverage drug delivery systems for patent extension
  - >understand when to use this strategy
  - >identify the right delivery system
  - >best technologies
  - >how generic companies are fighting back

Mel Sweitzer, PhD, Assistant Director, Pharmaceutical Sciences, Pfizer

11:45 *Luncheon*

1:15 **Understand the Impact of Impending Legislative Initiatives on Market Exclusivity Strategies**

- Review of current market exclusivity provisions, including
  - >data protection
  - >the generic drug approval process
  - >505(b)(2) drugs
  - >patent term extensions
  - >pediatric exclusivity
  - >orphan drugs
- Analysis of the stated motivations for, and potential impacts of
  - >proposed Hatch-Waxman reforms
  - >pending legislative changes in the Shumer-McCain and Leahy bills
- An update on
  - >the likely next-term changes
  - >the implications for market exclusivity strategies

Gregory J. Glover, MD, JD, Partner, Ropes & Gray

2:00 **Maximize Global Patent Protection as Part of the Lifecycle Planning Process**

- The benefits of managing a patent globally
- Resolve the tension between maximizing product lifecycle revenue on a global basis while ensuring reasonable prices
- The importance of "safe harbor" provision in the U.S. (35 U.S. Sec. 271(e)(1) of the Hatch-Waxman Act)
- Understand the impact of the European Union's (EU) challenge of the Canadian Patent Act's "safe harbor" provisions as a "stalking horse" for attack on U.S. "safe harbor" provisions
- "Safe harbor" held legal under TRIPS by World Trade Organization (WTO) dispute panel
- Pressure for worldwide "safe harbor" provisions resulting from the WTO dispute panel decision.
  - >need for a statutory "Bolar" exemption in the EU
- Update on the status of generic manufacturers' ability to work on drugs prior to patent expiration in major European markets

Jill A. Orr, Esq., Principal, Fish & Richardson

2:45 *Networking and Refreshment Break*

3:00 **The Patent Extension Application Process — Expectations vs. Reality**

- Overview of recent rulings
- What's working, what's not?
- Factors that impact the probability of getting approval
- Financial costs
- Timelines

Mark Fabes, Esq., Chief Patent Counsel to, Alexion Pharmaceuticals, Inc.

3:45 **Patent Adverse Event Profiles — A Competitive Necessity**

Companies have patented new expanded uses and novel dosing schedules of drugs in the past. Recently the U.S. Patent and Trade Office has indicated that new, safer uses of a drug are patentable (US 6,219,674) where the safer use involves disclosing of new adverse event information. Your company may maintain proprietary control of its drugs after their composition patents have expired by the discovery and patenting of new adverse event information. Learn how to profit from the discovery of new adverse event information on your products. Learn why patenting the adverse event profiles of drugs is essential to competitive today's market.

- Increase profits while making your products safer
- Develop a low cost patent portfolio of adverse events
- Learn about the risks of allowing your competitors to find new adverse events of your drugs
- Prevent "me too" drugs by discovering class related adverse events

Jan B. Cassin, MD, MBA, CEO, Classen Immunotherapies, Inc.

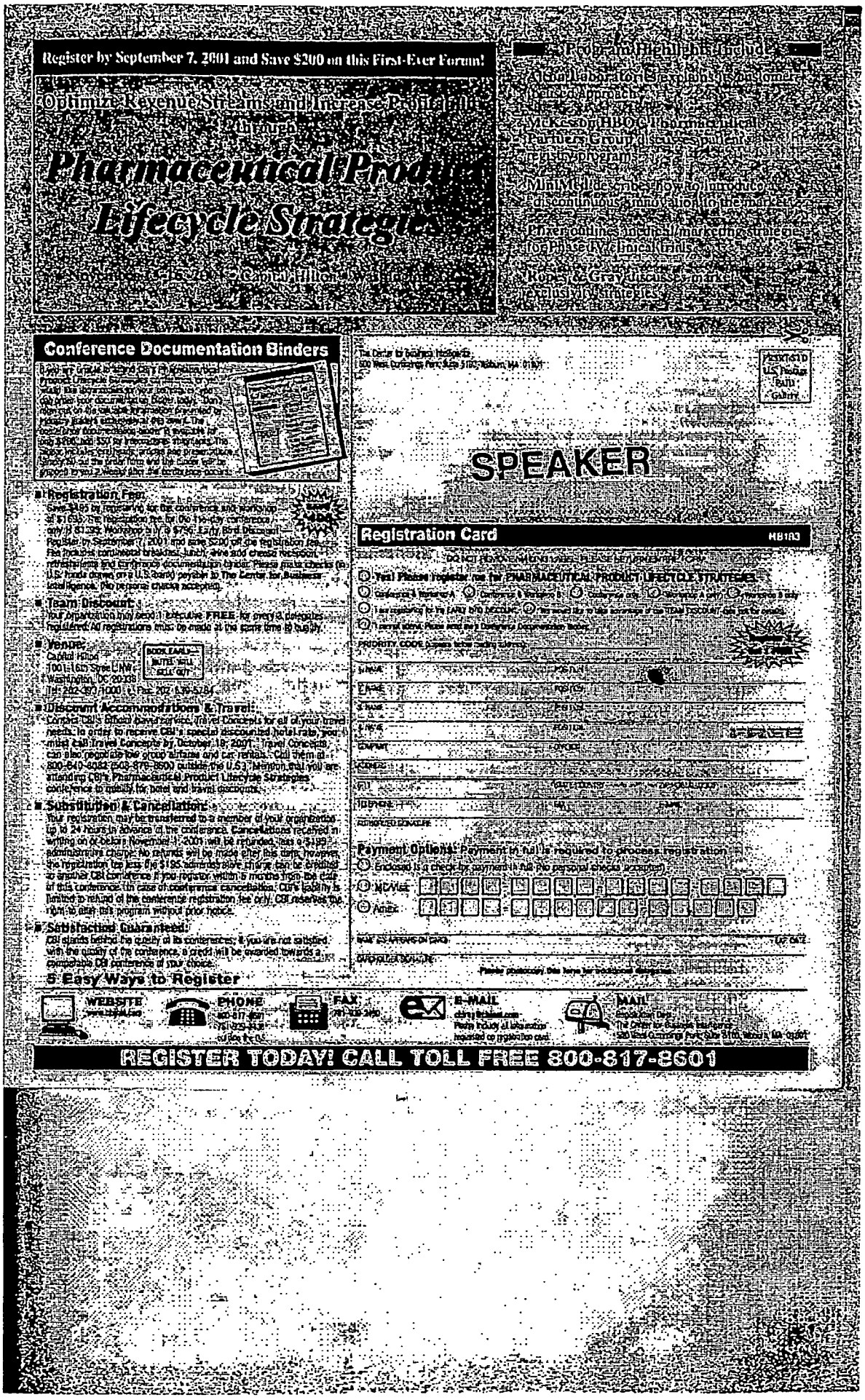
4:30 *Close of Conference*

Who Should Attend?

Vice Presidents and Directors of:

Marketing
Business Development
Alliances
Product Development
Licensing
Corporate Development
Strategic Planning

Best Available Copy



Hi John,

Here is the confirmation for the teleconference with Steve Cartt.

Subject: AE Patent Strategies
When: Friday, January 11th
Time: 5pm - 6pm EST; 2pm-3pm PST
Participants: Steve Cartt, Nancy Santilli, Jean Duvall, Mark Hoch (unconfirmed)

Call in information: 1-800-525-2464
Passcode: 537996
Call Owner: Steve Cartt

Let me know if you need any more information. I can be reached at 858-457-7461.
Have a great meeting,

Paula Chapman
Elan Pharmaceuticals
Administrative Assistant, Strategic Marketing
Telephone: 858-457-7461
Fax: 858-558-3713
E-mail: paula.chapman@elan.com

Bart -- great suggestions. I appreciate your help on these matters, and I feel confident we will make this work. Will keep you posted.....Steve

-----Original Message-----
From: Bart Classen [mailto:classen@vaccines.net]
Sent: Tuesday, May 21, 2002 4:57 AM
To: Cartt, Steve
Subject: patents

J. Barthelow Classen, M.D., M.B.A.
President and Chief Executive Officer
U.S.A.
Classen Immunotherapies, Inc.
Tel : 410.377.4549
Classen@vaccines.net
Fax : 410.377.8526

6517 Montrose Avenue
Baltimore, MD 21212

e-mail:

May 22, 2002

Mr. Steve Cartt
Elan Pharmaceuticals
800 Gateway Boulevard
South San Francisco
San Francisco, CA 94080

Dear Steve,

I spoke to Ms. Duvall yesterday and made the following suggestions for you
consideration.

* You may be able to discover additional information on the existing adverse event, or any other adverse event as described below, to allow you to obtain a patent. For example the adverse event may be more common or limited to people with predisposing conditions such as race, age, sex, prior medical conditions, or taking OTC medicines. Also the adverse event may be specific to one Cox-2 inhibitor or to all Cox-2 inhibitors. Either way you can obtain a patent.

If the adverse event is only present with one but not all Cox-2 you

can
claim: a method of administering your drug with one or more Cox-2 inhibitors excluding VIOX.

If the adverse event is found with all Cox-2 inhibitors you can claim: A
methods administering your drug with one or more NSAIDs excluding the class of Cox-2 inhibitors

If the adverse event is found with all compounds with a similar side chain, Y, you can claim: A method of reducing adverse event X associated with you drug by avoiding the coadministration of drugs containing side chain Y.

If the adverse event involves dizzyness or drawsyness one could determine
if a warning about opertaing a car, plane, machinery is appropriate or if there is an additive effect with OTCs like Benadryl that also cause drawsiness.

* If you can not find new patentable information described above you may be able to license the invention, discovery of the adverse event, from the person who first described the adverse event or who first described an association (series of adverse events). There may be several different inventions so there may be several different inventors. One may be willing to license the invention.

* You may want to use additional databases to search for adverse events even if the current adverse event is patentable. Discovery of additional patentable adverse event information will strengthen your patent position. You could use your information pertaining to reports of possible adverse events to formulate ideas for epidemiology studies. You could generate patentable adverse event information by simply following up on some of the suggested adverse events listed in your product insert. For example you can search an outside database for safety information on "chronic use" and to generate human data to expand on the animal toxicity, in particular cardiovascular and ophthalmic complications. Information can be obtained on side effects when used during labor, pregnancy, pediatrics, and in the elderly. The epidemiology studies can be performed in one or more of the many existing databases. Several examples include Kaiser Permanente and LDS

Hospital in Salt Lake City. Kaiser's database has information on outpatients and inpatients while LDS is limited solely to inpatients.

* If you desire additional help in locating patentable adverse event information I am available for hire as a consultant.

I will send you information on databases today.

Sincerely,

Bart

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Bart -- in terms of "prior art" concersn taht we had had, we actually seem to be ok on the drug interaction opportunity we had discussed. Right now we are working to collect some additional information to strengthen our position related to this strategy. Will keep you posted. REgards, Steve

-----Original Message-----
From: Bart Classen [mailto:classen@vaccines.net]
Sent: Thursday, June 13, 2002 5:26 AM
To: Cartt, Steve
Subject: Adverse events

I am writing to enquire how things are going. Have you found a data source willing to help you or are you still in serach of one? I tried to call you but you have not been in. If you need more ideas we should talk some more.

Bart Classen

PRESS RELEASE

Contacts:
James E. Green, Executive Vice President, Corporate Affairs
423-989-8125
David E. Robinson, Senior Director, Corporate Affairs
423-989-7045

King Pharmaceuticals

FOR IMMEDIATE RELEASE

KING PHARMACEUTICALS REPORTS THIRD-QUARTER 2006 FINANCIAL RESULTS

BRISTOL, TENNESSEE, November 9, 2006 - King Pharmaceuticals, Inc. (NYSE:KG) announced today that total revenues were $492 million during the third quarter ended September 30, 2006, compared to $518 million in the third quarter of 2005. Including special items, net earnings equaled $90 million and diluted earnings per share equaled $0.37 during the third quarter ended September 30, 2006, compared to net income of $122 million and diluted earnings per share of $0.50 in the same period of the prior year. Excluding special items, net earnings equaled $106 million and diluted earnings per share equaled $0.44 during the third quarter ended September 30, 2006, compared to net earnings of $125 million and diluted earnings per share of $0.52 in the third quarter of 2005.

For the nine-month period ended September 30, 2006, total revenues were $1.48 billion compared to $1.35 billion for the nine-month period ended September 30, 2005. Including special items, net income equaled $252 million and diluted earnings per share equaled $1.04 during the nine-month period ended September 30, 2006, compared to net income of $212 million and diluted earnings per share of $0.88 during the same period of the prior year. Excluding special items, net earnings equaled $324 million and diluted earnings per share equaled $1.33 for the nine-month period ended September 30, 2006, compared to net earnings of $308 million and diluted earnings per share of $1.27 in the same period of 2005.

Brian A. Markison, President and Chief Executive Officer of King, stated, "We are pleased with our continued solid financial performance and our accomplishments during the third quarter. Importantly, we strengthened our portfolio with the launch of Glumetza™, a new generation metformin product for patients with Type II diabetes, and our agreement to acquire the rights to Avinza®, a true once-a-day morphine product."

Mr. Markison emphasized, "Glumetza™ is an excellent complement to our cardiovascular/metabolics franchise and Avinza® significantly strengthens our growing pain portfolio, positioning us to become a leader in pain management. We expect to close the Avinza® acquisition on or about December 31, 2006. In the interim, our sales force is promoting the product pursuant to a separate copromotion agreement which terminates in January 2007."

Mr. Markison added, "We are continuing to focus on business development opportunities in our key therapeutic areas to further improve our development pipeline, which includes four products in Phase III and two products in Phase II. Additionally, we expect T-62, our investigational drug for the treatment of neuropathic pain, to enter Phase II in the first half of 2007. As our pipeline continues to build momentum, we expect to report results from several key clinical programs next year."

Net revenue from branded pharmaceuticals totaled $433 million for the third quarter of 2006, a 5% decrease from $455 million during the third quarter of 2005. This difference was primarily due to previously disclosed changes in reserve estimates and increases in wholesale inventory levels of the Company's products in the third quarter of 2005 that each positively benefited net revenues during that quarter.

Altace® (ramipril) net sales totaled $159 million during the third quarter of 2006 compared to $174 million during the third quarter of 2005.

Net sales of Skelaxin® (metaxalone) totaled $106 million during the third quarter of 2006 compared to $116 million during the same period of the prior year.

Thrombin-JMI® (thrombin, topical, bovine, USP) net sales totaled $70 million during the third quarter of 2006 compared to $54 million during the third quarter of 2005. Net sales of this product during the third quarter of 2006 benefited from an increase in wholesale inventory levels which remain within a normalized range.

Net sales of Sonata® (zaleplon) totaled $19 million during the third quarter of 2006 compared to $20 million during the third quarter of the prior year.

Levoxyl® (levothyroxine sodium tablets, USP) net sales totaled $25 million during the third quarter ended September 30, 2006 compared to $36 million during the third quarter of 2005.

King's Meridian Medical Technologies business contributed revenue totaling $37 million during the third quarter of 2006 compared to $38 million during the same period of the prior year.

Royalty revenues, derived primarily from Adenoscan® (adenosine), totaled $19 million during the third quarter ended September 30, 2006, compared to $22 million during the third quarter of 2005. During the third quarter ended September 30, 2006, net revenue from contract manufacturing equaled $3 million.

As of September 30, 2006, the Company's cash and cash equivalents and investments in debt securities totaled approximately $918 million. During the third quarter of 2006, the Company generated cash flow from operations of approximately $127 million. King expects to use cash to consummate its planned acquisition of Avinza®. Additionally, King plans to utilize its cash position to fuel its business development initiatives and aggressively invest in the further development of products in its pipeline. Accordingly, the Company continues to believe that its total investment in research and development for the full year of 2006 could exceed $150 million.

Webcast Information

King will conduct a webcast today to discuss the Company's third quarter 2006 financial results and other matters pertaining to its business. Interested persons may listen to the webcast on

Thursday, November 9, 2006, at 11:00 a.m., E.S.T. by clicking the following link to register and then joining the live event with the same URL:

http://www.kingpharm.com/web_casts.asp

If you are unable to participate during the live event, the webcast will be archived on King's web site at the same link for not less than 14 days after the webcast.

About Glumetza™

Glumetza™ is a once-daily, extended-release formulation of metformin HCl indicated as an adjunct to diet and exercise to improve glycemic control in adult patients (18 years and older) with Type II diabetes. Glumetza™ may be used concomitantly with a sulfonylurea or insulin to improve glycemic control in adults.

Glumetza™ is contraindicated in patients with renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels greater than or equal to 1.5 mg/dL in males and greater than or equal to 1.4 mg/dL in females), congestive heart failure, known hypersensitivity to metformin HCl, and acute or chronic metabolic acidosis, including diabetic ketoacidosis with or without coma. As with all metformins, there is a warning regarding lactic acidosis with Glumetza™. For additional information on the product, please access the package insert at http://www.depomedinc.com/glumetza_Prescribing_Info.pdf.

About Avinza®

Avinza® is an extended-release opioid agent for patients requiring continuous, around-the-clock analgesia for an extended period of time. It is ideally suited for low-risk populations for the treatment of cancer and severe, chronic non-malignant pain conditions. It contains morphine in an extended release form, allowing for once-daily dosing. Avinza® is covered by a formulation patent that extends through November 2017.

Because Avinza® is an extended-release product, it should not be chewed, crushed, or dissolved due to the risk of rapid release and absorption of a potentially fatal dose of morphine. Avinza® should not be taken with alcohol or drug products containing alcohol. The most common serious adverse events reported with administration of Avinza® are vomiting, nausea, death, dehydration, dyspnea, and sepsis. Avinza® is contraindicated in patients with known hypersensitivity to morphine, morphine salts, or any components of the product.

About Special Items

Under Generally Accepted Accounting Principles ("GAAP"), "net earnings" and "diluted earnings per share" include special items. In addition to the results determined in accordance with GAAP, King provides its net earnings and diluted earnings per share results for the quarters and nine months ended September 30, 2006 and 2005, excluding special items. These non-GAAP financial measures exclude special items which are those particular material income or expense items that King considers to be unrelated to the Company's ongoing, underlying

business, non-recurring, or not generally predictable. Such items include, but are not limited to, merger and restructuring expenses; non-capitalized expenses associated with acquisitions, such as in-process research and development charges and one-time inventory valuation adjustment charges; charges resulting from the early extinguishment of debt; asset impairment charges; expenses of drug recalls; and gains and losses resulting from the divestiture of assets. King believes the identification of special items enhances the analysis of the Company's ongoing, underlying business and the analysis of the Company's financial results when comparing those results to that of a previous or subsequent like period. However, it should be noted that the determination of whether to classify an item as a special item involves judgments by King's management. A reconciliation of non-GAAP financial measures referenced herein and King's financial results determined in accordance with GAAP is provided below.

About King Pharmaceuticals

King, headquartered in Bristol, Tennessee, is a vertically integrated branded pharmaceutical company. King, an S&P 500 Index company, seeks to capitalize on opportunities in the pharmaceutical industry through the development, including through in-licensing arrangements and acquisitions, of novel branded prescription pharmaceutical products in attractive markets and the strategic acquisition of branded products that can benefit from focused promotion and marketing and product life-cycle management.

Forward-looking Statements

This release contains forward-looking statements which reflect management's current views of future events and operations, including, but not limited to, statements pertaining to the planned closing of the Avinza® acquisition; statements pertaining to the expected reporting of clinical trial results; statements pertaining to the Company's business development initiatives and product pipeline; statements pertaining to the Company's expected investment in research and development for 2006; statements pertaining to the Company's planned use of cash; and statements pertaining to the Company's planned webcast to discuss its third-quarter 2006 results. These forward-looking statements involve certain significant risks and uncertainties, and actual results may differ materially from the forward-looking statements. Some important factors which may cause actual results to differ materially from the forward-looking statements include dependence on King's ability to continue to acquire branded products, including products in development; dependence on King's ability to continue to successfully execute the Company's strategy and to continue to capitalize on strategic opportunities in the future for sustained long-term growth; dependence on King's ability to successfully integrate its acquisitions; dependence on King's ability to complete its acquisition of Avinza® as planned; dependence on the high cost and uncertainty of research, clinical trials, and other development activities involving pharmaceutical products in which King has an interest; dependence on the unpredictability of the duration and results of the U. S. Food and Drug Administration's ("FDA") review of Investigational New Drug applications ("IND"), New Drug Applications ("NDA"), and Abbreviated New Drug Applications ("ANDA") and/or the review of other regulatory agencies worldwide that relate to those projects; dependence on the availability and cost of raw materials; dependence on no material interruptions in supply by contract manufacturers of King's products;

dependence on the potential effect on sales of the Company's existing branded pharmaceutical products as a result of the potential development and approval of a generic substitute for any such product or other new competitive products; dependence on the potential effect of future acquisitions and other transactions pursuant to the Company's growth strategy; dependence on whether King incurs research and development expenses as planned; dependence on King's compliance with FDA and other government regulations that relate to the Company's business; dependence on King's ability to conduct its webcast as currently planned on November 9, 2006; dependence on changes in general economic and business conditions; changes in current pricing levels; changes in federal and state laws and regulations; changes in competition; unexpected changes in technologies and technological advances; and manufacturing capacity constraints. Other important factors that may cause actual results to differ materially from the forward-looking statements are discussed in the "Risk Factors" section and other sections of King's Form 10-K for the year ended December 31, 2005 and Form 10-Q for the quarter ended June 30, 2006, which are on file with the U.S. Securities and Exchange Commission ("SEC"). King does not undertake to publicly update or revise any of its forward-looking statements even if experience or future changes show that the indicated results or events will not be realized.

KING PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	September 30, 2006 (Unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 138,054	$ 30,014
Investments in debt securities	779,545	494,663
Restricted cash	-	130,400
Accounts receivable, net	255,746	223,581
Inventories	186,770	228,063
Deferred income tax assets	69,153	81,777
Prepaid expenses and other current assets	102,356	59,291
Total current assets	1,531,624	1,247,789
Property, plant and equipment, net	303,822	302,474
Intangible assets, net	924,828	967,194
Goodwill	121,152	121,152
Deferred income tax assets	258,498	231,032
Marketable securities	13,508	18,502
Other assets	94,112	77,099
Total assets	$ 3,247,544	$ 2,965,242
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 80,810	$ 84,539
Accrued expenses	471,695	519,620
Income taxes payable	20,617	22,301
Current portion of long-term debt	4,257	345,000
Total current liabilities	577,379	971,460
Long-term debt	400,000	-
Other liabilities	23,894	20,360
Total liabilities	1,001,273	991,820
Commitments and contingencies		
Shareholders' equity:		
Common shares no par value, 300,000,000 shares authorized, 243,113,666 and 242,493,416 shares issued and outstanding, respectively	1,238,535	1,213,482
Retained earnings	1,006,938	754,953
Accumulated other comprehensive income	798	4,987
Total shareholders' equity	2,246,271	1,973,422
Total liabilities and shareholders' equity	$ 3,247,544	$ 2,965,242

KING PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
REVENUES:				
Total revenues	$ 491,706	$ 518,032	$ 1,475,586	$ 1,349,596
OPERATING COSTS AND EXPENSES:				
Cost of revenues , exclusive of depreciation, amortization and impairments shown below	106,473	92,257	305,925	257,259
Excess purchase commitment	-	-	-	(1,582)
Total cost of revenues	106,473	92,257	305,925	255,677
Selling, general and administrative, exclusive of co-promotion fees and Mylan transaction costs	112,802	107,232	320,517	292,643
Special legal and professional fees	(5,502)	4,406	(1,037)	13,268
Mylan transaction costs	-	466	-	3,898
Co-promotion fees	50,294	70,346	162,615	162,588
Total selling, general, and administrative expense	157,594	182,450	482,095	472,397
Depreciation and amortization	36,361	31,352	109,273	112,698
Accelerated depreciation	1,472	-	1,472	-
Total depreciation and amortization	37,833	31,352	110,745	112,698
Research and development	38,419	24,049	102,931	53,021
Research and development-in-process upon acquisition	25,000	-	110,000	-
Total research and development	63,419	24,049	212,931	53,021
Intangible asset impairment	-	-	279	126,923
Restructuring charges	3,202	597	3,194	2,603
Gain on sale of products	-	(20)	-	(1,458)
Total operating costs and expenses	368,521	330,685	1,115,169	1,021,861
OPERATING INCOME	123,185	187,347	360,417	327,735
OTHER INCOME (EXPENSE):				
Interest expense	(1,894)	(3,136)	(7,925)	(8,876)
Interest income	8,489	5,253	22,842	11,463
Gain (loss) on investment	-	1,040	-	(6,182)
(Loss) gain on early extinguishment of debt	(11)	-	698	-
Other, net	101	(751)	(613)	(2,047)
Total other income (expense)	6,685	2,406	15,002	(5,642)
INCOME FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	129,870	189,753	375,419	322,093
Income tax expense	40,020	67,109	123,931	111,302
INCOME FROM CONTINUING OPERATIONS	89,850	122,644	251,488	210,791
DISCONTINUED OPERATIONS:				
Income (loss) from discontinued operations	865	(1,226)	775	2,607
Income tax expense (benefit)	310	(439)	278	989
Total income (loss) from discontinued operations	555	(787)	497	1,618
NET INCOME	$ 90,405	$ 121,857	$ 251,985	$ 212,409
Basic net income per common share	$ 0.37	$ 0.50	$ 1.04	$ 0.88
Diluted net income per common share	$ 0.37	$ 0.50	$ 1.04	$ 0.88
Shares used in basic net income per share	242,256	241,755	242,163	241,737
Shares used in diluted net income per share	242,798	241,907	242,711	241,831

KING PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
EXCLUDING SPECIAL ITEMS - NON GAAP
(in thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
REVENUES:				
Total revenues	$ 491,706	$ 518,032	$ 1,475,586	$ 1,349,596
OPERATING COSTS AND EXPENSES:				
Cost of revenues , exclusive of depreciation and amortization shown below	108,473	92,257	305,925	257,259
Selling, general and administrative, exclusive of co-promotion fees and Mylan transaction costs	112,802	107,232	320,517	292,643
Co-promotion fees	50,294	70,346	162,615	162,588
Total selling, general, and administrative expense	163,096	177,578	483,132	455,231
Depreciation and amortization	36,361	31,352	109,273	112,698
Research and development	38,419	24,049	102,931	53,021
Total operating costs and expenses	344,349	325,236	1,001,261	878,209
OPERATING INCOME	147,357	192,796	474,325	471,387
OTHER INCOME (EXPENSE):				
Interest expense	(1,894)	(3,136)	(7,925)	(8,876)
Interest income	8,489	5,253	22,842	11,463
Other, net	101	(751)	(613)	(2,047)
Total other income	6,696	1,366	14,304	540
INCOME BEFORE INCOME TAXES	154,053	194,162	488,629	471,927
Income tax expense	48,430	68,797	164,690	163,767
NET INCOME	$ 105,623	$ 125,365	$ 323,939	$ 308,160
Basic net income per common share	$ 0.44	$ 0.52	$ 1.34	$ 1.27
Diluted net income per common share	$ 0.44	$ 0.52	$ 1.33	$ 1.27
Shares used in basic net income per share	242,256	241,755	242,163	241,737
Shares used in diluted net income per share	242,798	241,907	242,711	241,831

KING PHARMACEUTICALS, INC.
RECONCILIATION OF NON-GAAP MEASURES
(in thousands, except per share data)
(Unaudited)

The following tables reconcile Non-GAAP measures to amounts reported under GAAP:

	Three Months Ended September 30, 2006	EPS	Nine Months Ending September 30, 2006	EPS
Net income, excluding special items	$ 105,623		$ 323,939	
Diluted income per common share, excluding special items		$ 0.44		$ 1.33
SPECIAL ITEMS:				
Special legal and professional fees (selling, general, and administrative)	5,502	0.02	1,037	0.01
Accelerated depreciation (other operating costs and expenses)	(1,472)	(0.01)	(1,472)	(0.01)
Research and development -in-process upon acquisition (other operating costs and expenses)	(25,000)	(0.10)	(110,000)	(0.45)
Intangible asset impairment (other operating costs and expenses)	-	-	(279)	(0.00)
Restructuring charges (other operating costs and expenses)	(3,202)	(0.01)	(3,194)	(0.01)
(Loss) gain on early extinguishment of debt (other income (expense))	(11)	(0.00)	698	0.00
Income from discontinued operations	865	0.00	775	0.00
Income tax benefit from special items	8,100	0.03	40,481	0.17
Net income	$ 90,405		$ 251,985	
Diluted income per common share, as reported under GAAP		$ 0.37		$ 1.04

	Three Months Ended September 30, 2005	EPS	Nine Months Ending Septmeber 30, 2005	EPS
Net income, excluding special items	$ 125,365		$ 308,160	
Diluted income per common share, excluding special items		$ 0.52		$ 1.27
SPECIAL ITEMS:				
Excess purchase commitment (cost of goods sold)	-	-	1,582	0.01
Special legal and professional fees (selling, general, and administrative)	(4,406)	(0.02)	(13,268)	(0.05)
Mylan transaction costs (selling, general, and administrative)	(466)	(0.00)	(3,898)	(0.02)
Intangible asset impairment (other operating costs and expenses)	-	-	(126,923)	(0.52)
Restructuring charges (other operating costs and expenses)	(597)	(0.00)	(2,603)	(0.01)
Gain on sale of products (other operating costs and expenses)	20	0.00	1,458	0.01
Gain (loss) on investment (other income (expense))	1,040	0.00	(6,182)	(0.03)
(Loss) income from discontinued operations	(1,226)	(0.01)	2,607	0.01
Income tax benefit from special items	2,127	0.01	51,476	0.21
Net income	$ 121,857		$ 212,409	
Diluted income per common share, as reported under GAAP		$ 0.50		$ 0.88

KING PHARMACEUTICALS, INC.

SUMMARY RECONCILIATION OF SPECIAL ITEMS FOR THE QUARTERS ENDED SEPTEMBER 30, 2006 AND 2005

King recorded special items during the third quarter ended September 30, 2006, resulting in a net charge of $23 million, or $15 million net of tax, primarily due to a $25 million charge related to acquired in-process research and development associated with King's collaboration with Arrow and certain of its affiliates to commercialize novel formulations of Altace®.

During the three months ended September 30, 2005, King recorded special items resulting in a net charge of $6 million, or $4 million net of tax, primarily due to professional fees associated with government inquiries and private plaintiff securities litigation.

KING PHARMACEUTICALS, INC.
SUMMARY RECONCILIATION OF SPECIAL ITEMS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2006 AND 2005

King recorded special items during the nine months ended September 30, 2006, resulting in a net charge of $112 million, or $72 million net of tax, primarily due to $110 million in charges related to acquired in-process research and development associated with King's entry into a strategic collaboration with Arrow and certain of its affiliates to commercialize novel formulations of Altace®.

During the nine months ended September 30, 2005, King recorded special items resulting in a net charge of $147 million, or $96 million net of tax, primarily due to an intangible asset impairment charge related to Sonata®.

EXECUTIVE OFFICES

KING PHARMACEUTICALS, INC.
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